U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(kml)
FOLDER:	K151204 - 379 pages
COMPANY:	CORELEADER BIOTECH CO., LTD. (COREBIOT)
PRODUCT:	DRESSING, WOUND, DRUG (FRO)
SUMMARY:	Product: HEMO-BANDAGE
DATE REQUESTED:	May 12, 2016
DATE PRINTED:	May 12, 2016
Note:	Printed

K151204/A001

Chapter 3 510(k) Cover letter

康力得生技股份有限公司
CoreLeader Biotech CO., LTD
22102 新北市汐止區新台五路一段100號19樓

Date: 6th June 2015

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center WO66-G609
10903 New Hampshire Avenue, Silver Spring, Maryland 20993-0002

Traditional 510(k): New Device Submission

Device Name:	CoreLeader HEMO-Bandage
Common Name:	Topical wound dressing
K Number:	unknown
Class	Unclassified
Panel	General & Plastic Surgery
510(k) Submitter:	CoreLeader Biotech Co., Ltd. 19F, No. 100, Sec. 1, Xintai 5th Rd., Xizhi Dist., New Taipei City, Taiwan, R.O.C. 22102 Phone: +886-2-26968880 Fax: +886-2-26968882
Contact Person:	Ya-Wen Kuo Director, Regulatory and R&D 19F, No. 100, Sec. 1, Xintai 5th Rd., Xizhi Dist., New Taipei City, Taiwan, R.O.C. 22102 Phone: +886-2-26968880 FAX: +886-2-26968882 E-mail: ywk@coreleaderbio.com
eCopy Statement:	The eCopy is an exact duplicate of the paper copy.

康力得生技股份有限公司
CoreLeader Biotech CO., LTD
22102 新北市汐止區新台五路一段100號19樓

FDA CDRH DMC

JUN 10 2015

Received

Dear Dr. Arepalli,

Warm greeting from Coreleader Biotech Co., Ltd.

First of all, we appreciates your effort on reviewing our case very much. To further demonstrate the efficacy and safety of HEMO-Bandage, we hereby submits our new animal study which employs the *in vivo* hemorrhage model b(4) [redacted]
This study contains more detailed hematologic parameters, tissue histology and b(4) [redacted] compared to the previous one. We believe this study will further prove HEMO-Bandage is of the similar safety and efficacy as the predicate device, i.e. Combat Gauze. Please kindly take this study into your reviewing.

If there are any questions, please feel free to contact me at the aforementioned contact information.

Sincerely,

Ya-Wen Kuo

Ya-Wen Kuo
Director, Regulatory and R&D
CoreLeader Biotech Co., Ltd

b7

Chapter 3

510(k) Cover Letter

康力得生技股份有限公司
CoreLeader Biotech CO., LTD
22102 新北市汐止區新台五路一段100號19樓

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eCopy Statement:	The eCopy is an exact duplicate of the paper copy.

康力得生技股份有限公司
CoreLeader Biotech CO., LTD
22102 新北市汐止區新台五路一段100號19樓

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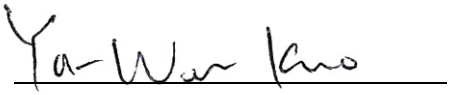
If there are any questions, please feel free to contact me at the aforementioned contact information.

Sincerely,



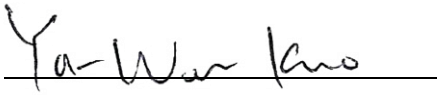
Ya-Wen Kuo
Director, Regulatory and R&D
CoreLeader Biotech Co., Ltd

Chapter 6

Truthful and Accurate Statement

Truthful and Accurate Statement

I certify that, in my capacity as Director of Regulatory and R&D of CoreLeader Biotech Co., Ltd, I believe, to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



Ya-Wen Kuo
Manager, Regulatory Affair
CoreLeader Biotech Co., Ltd

Ya-Wen Kuo
Typed Name

2015/06/04
Date

_____
*(Premarket Notification [510(k)] Number)

*For a new submission, leave the 510(k) number blank.

Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not a consultant for the 510(k) submitter].

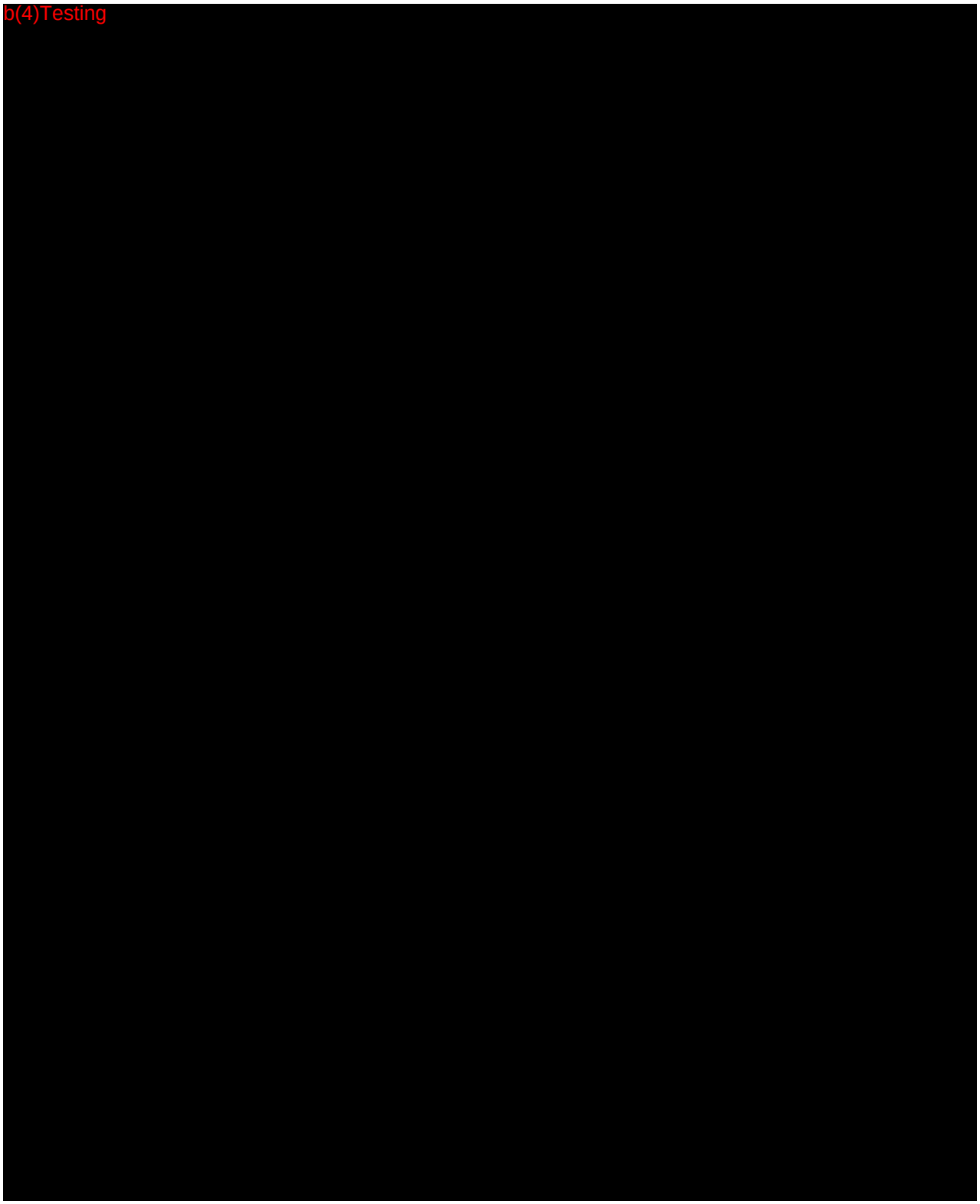
Chapter 19

Performance Testing – Animal

Chapter 19 Performance Testing – Animal

1. **The full study report is listed in Annex 1.**

b(4)Testing



Study Report

In vivo Hemostasis Performance of CoreLeader HEMO-bandage using Swine Model

Report No. b(4)Testing

康力得生技股份有限公司
CoreLeader Biotech CO., LTD
22102 新北市汐止區新台五路一段100號19樓

In vivo Hemostasis Performance of CoreLeader HEMO-bandage Using Swine Model

This study complied with the regulations of Ministry of Health and Welfare (MOHW), Taiwan, Organization for Economic Cooperation and Development (OECD), U.S. 21 CFR part 58.120 and 21 CFR part 58.185 on principles of Good Laboratory Practice for nonclinical laboratory studies. The study was conducted in accordance with an agreed protocol, and the results were truly recorded as they were. The characteristics and properties of the tested articles were provided by the sponsor—CoreLeader Biotech Co., Ltd.

(b) (6) MD, PhD
Study Director

2015/06/04
Date: June 4th, 2015

Ya-Wen Kuo
Ya-Wen Kuo, PhD
Director, Regulatory and R&D

2015/06/04
Date: June 4th, 2015

康力得生技股份有限公司
CoreLeader Biotech CO., LTD
22102 新北市汐止區新台五路一段100號19樓

Quality Assurance Statement

In compliance with regulations of Ministry of Health and Welfare (MOHW), Taiwan, Organization for Economic Cooperation and Development (OECD), U.S. 21 CFR part 58.120 and 21 CFR part 58.185, Department of Quality Control of CoreLeader Biotech inspected operator, facilities, equipment, test methods, raw data, and records of the study regularly. All original records, raw data, and documentations were truthfully addressed in the report.

Ya-Wen Kuo

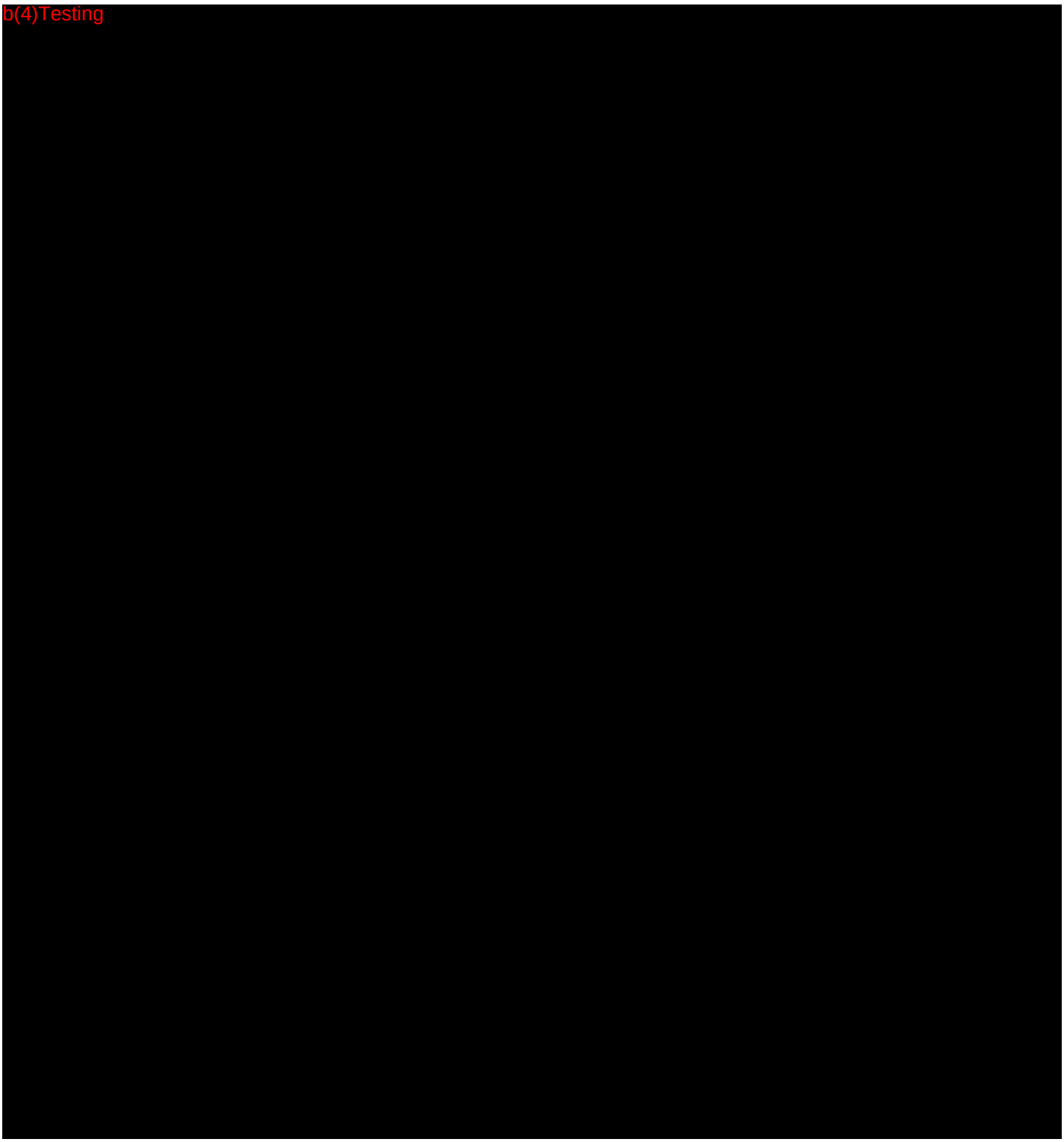
Ya-Wen Kuo, PhD
Director, Regulatory and R&D

2015/06/04

Date: June 4th, 2015

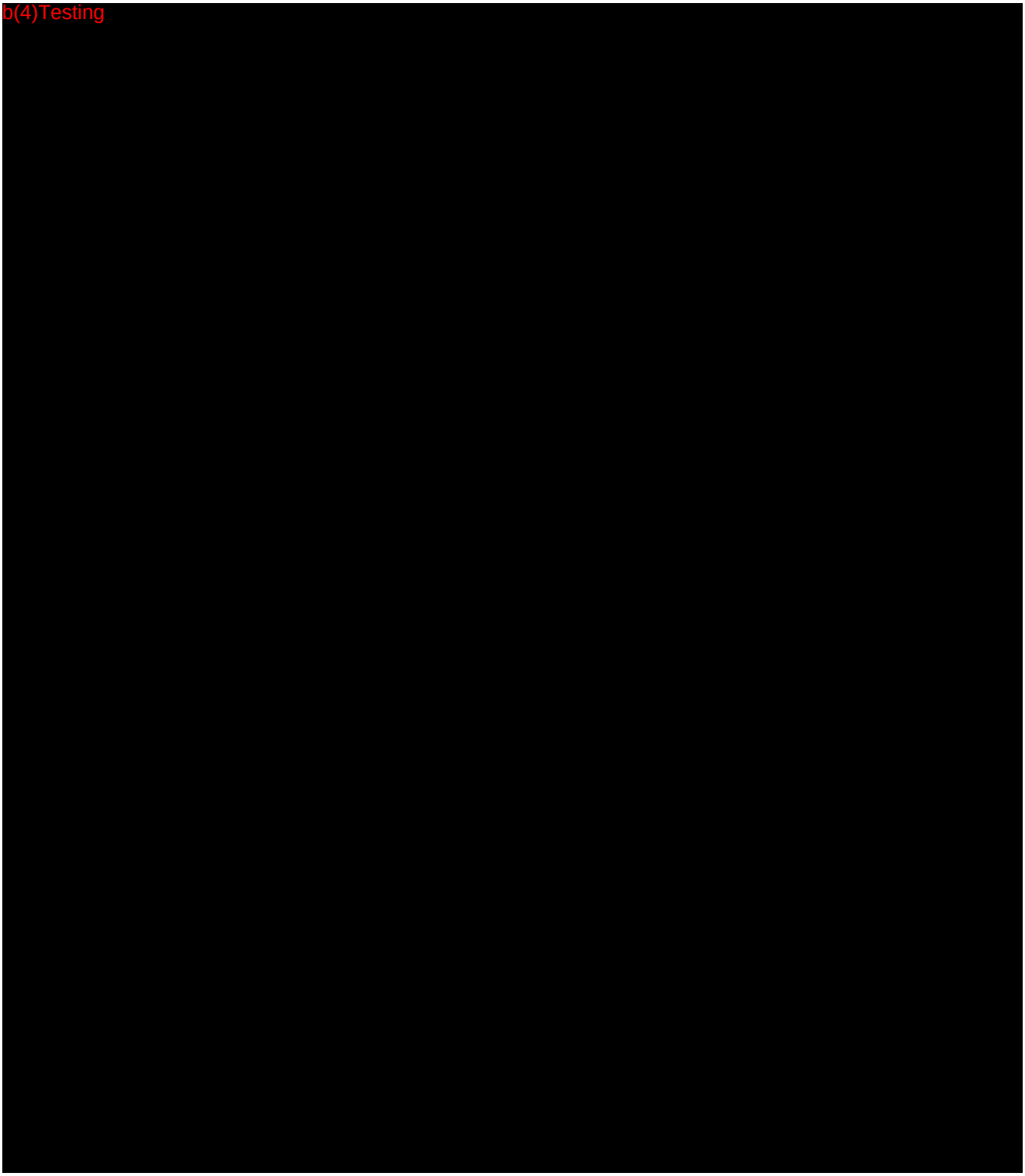
康力得生技股份有限公司
CoreLeader Biotech CO., LTD
22102 新北市汐止區新台五路一段100號19樓

b(4)Testing



康力得生技股份有限公司
CoreLeader Biotech CO., LTD
22102 新北市汐止區新台五路一段100號19樓

b(4)Testing



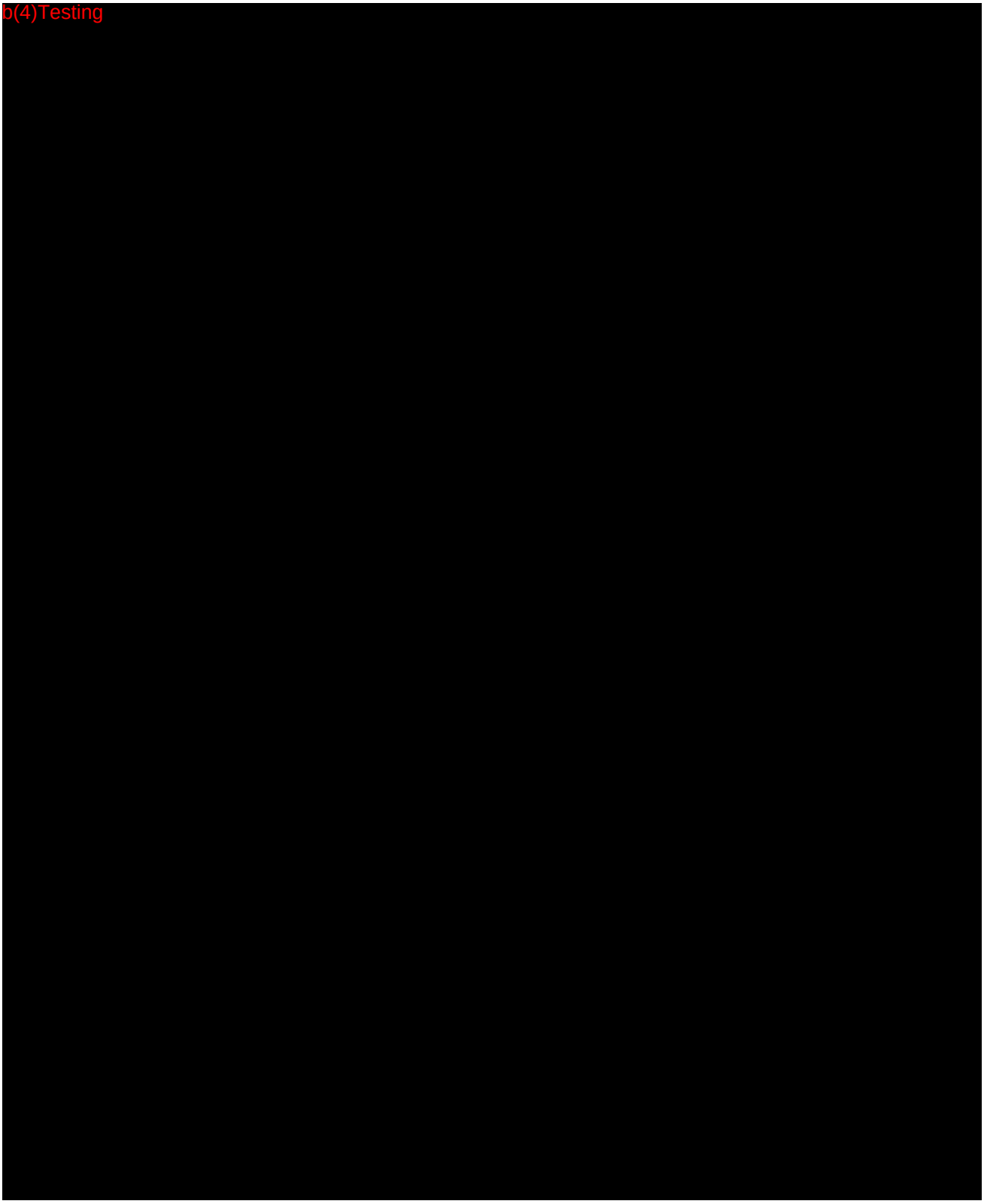
康力得生技股份有限公司
CoreLeader Biotech CO., LTD
22102 新北市汐止區新台五路一段100號19樓

b(4)Testing

[redacted]

康力得生技股份有限公司
CoreLeader Biotech CO., LTD
22102 新北市汐止區新台五路一段100號19樓

b(4)Testing



b(4)Testing

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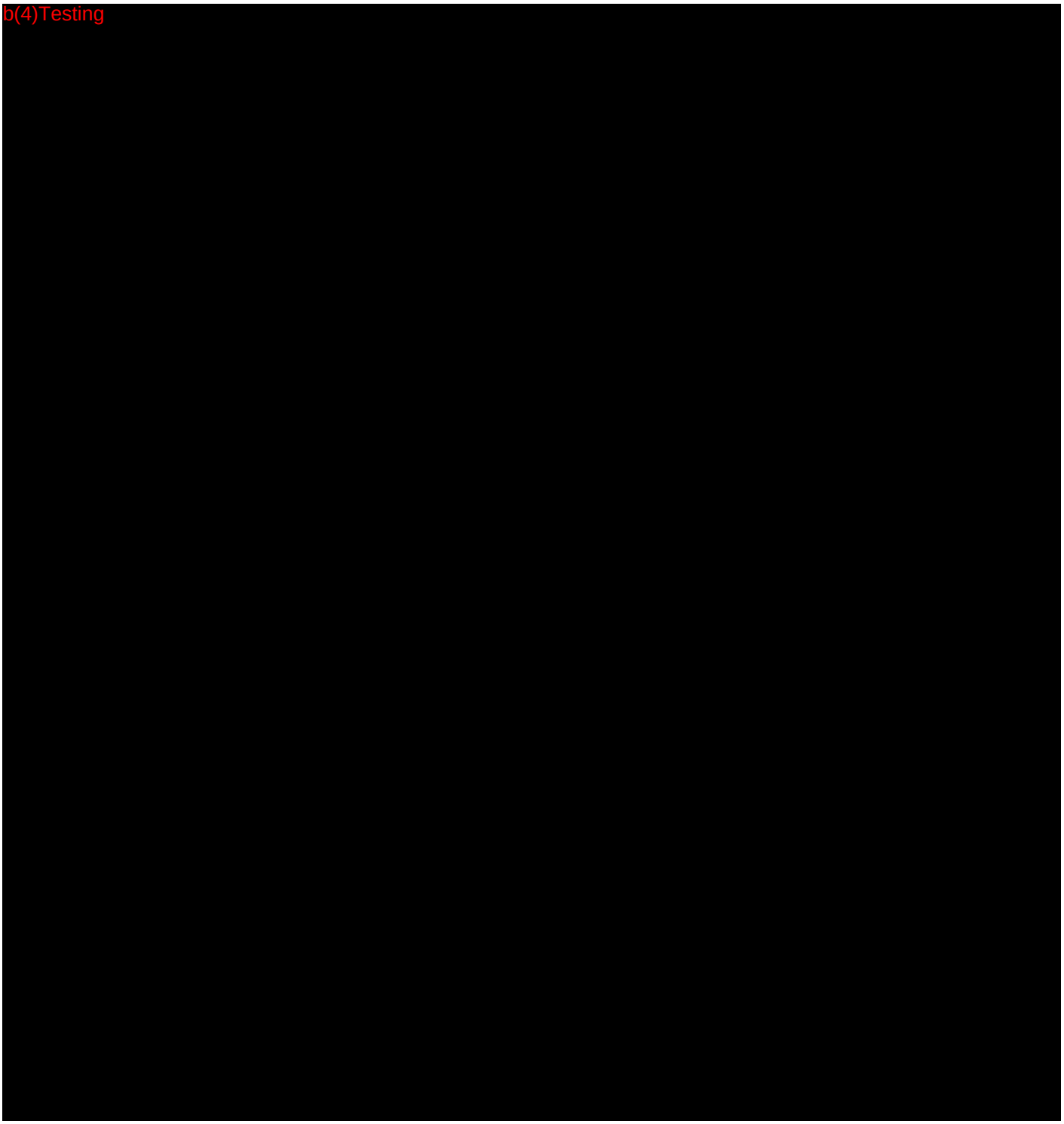
CoreLeader Biotech CO., LTD
22102 新北市汐止區新台五路一段100號19樓

b(4)Testing



b(4)Testing

康力得生技股份有限公司
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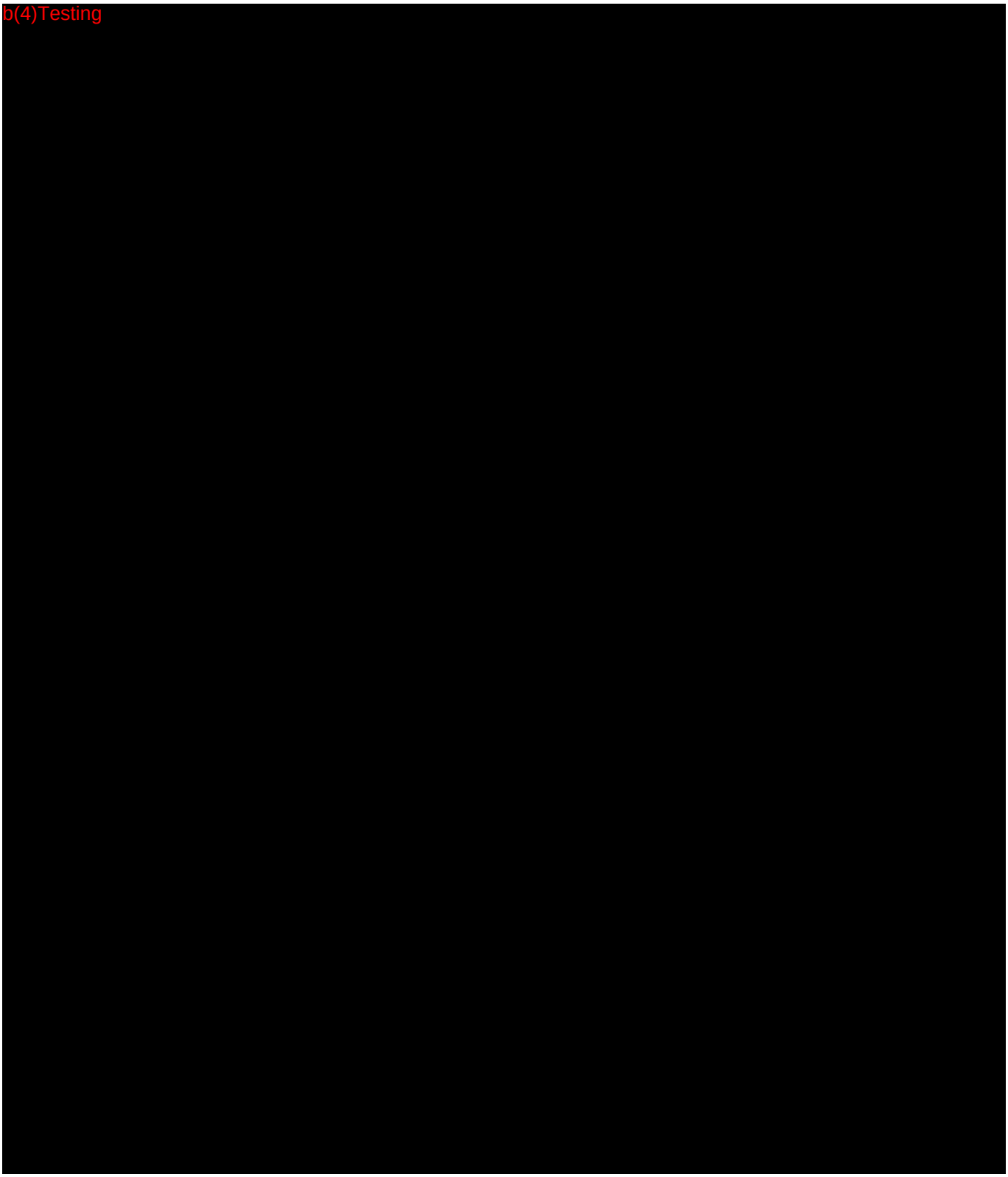
b(4)Testing



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CoreLeader Biotech CO., LTD
22102 新北市汐止區新台五路一段100號19樓

b(4)Testing

[redacted]

康力得生技股份有限公司
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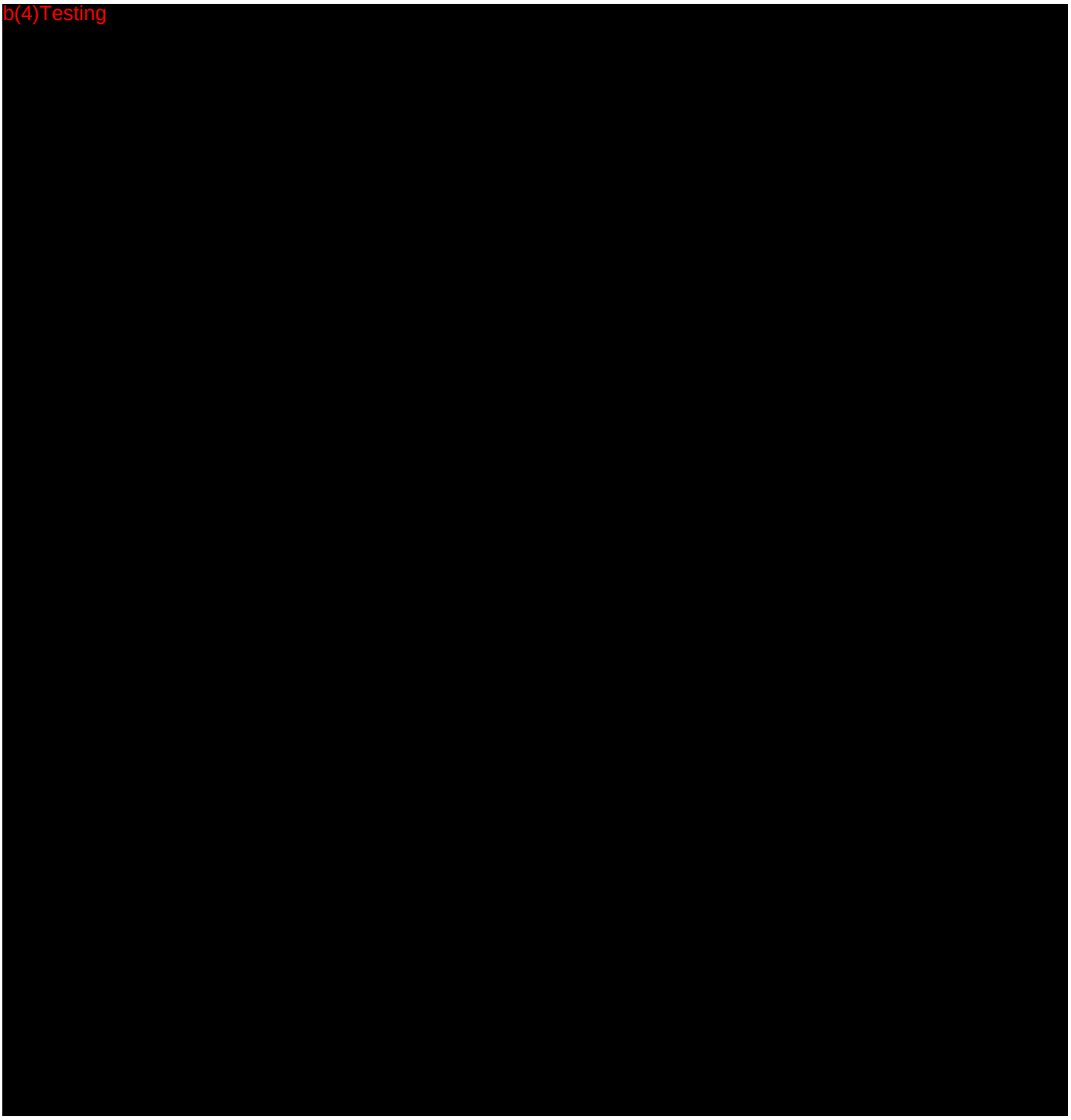
22102 新北市汐止區新台五路一段100號19樓

b(4)Testing



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b(4)Testing

[redacted]

康力得生技股份有限公司
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22102 新北市汐止區新台五路一段100號19樓

b(4)Testing

[redacted]

康力得生技股份有限公司
CoreLeader Biotech CO., LTD
22102 新北市汐止區新台五路一段100號19樓

b(4)Testing

[redacted]

b(6)Personal Information

b(6)Personal Information

b(6)Personal Information

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K151204

Chapter 3 510(k) Cover letter

康力得生技股份有限公司
CoreLeader Biotech CO., LTD
22102 新北市汐止區新台五路一段100號19樓

To whom it may concern,

Coreleader Biotech Co., Ltd hereby submits this Traditional 510(k): New Device to get substantial equivalence clearance for our new product CoreLeader HEMO-Bandage before marketing. This new device functions to manage moderate to severe bleedings resulted from traumatic wounds and reduce risk of wound infection as well. We believe CoreLeader HEMO-Bandage is of the similar safety and efficacy as the predicate devices since they have the same fundamental technologies and mode of actions.

This is b(4) ubmission of this medical device. The K-number of the previous submission is b(4) b(4)

The required information is briefed as follows,

1. ***The in vivo animal study lacks supportive data which show*** b(4) ***devices.***
2. ***The source of chitosan and manufacturing process used for the device are not clearly identified.***
3. ***Revise Indications for Statement to clearly*** b(4)
4. ***Provide the reasoning for*** b(4) ***for the measurement parameters in bench test.***
5. ***Please provide*** b(4) ***and*** b(4) ***from positive control testing completed within*** b(4) ***for the*** b(4)
6. ***Please provide the information regarding to the*** b(4)
7. ***Please provide evidence showing the medical device will no*** b(4)
8. ***Please provide the results of*** b(4)
9. ***Please indicate the*** b(4) ***in the device on the label.***

We incorporate the required data into each related chapter of this submission to present the complete evidence of substantial equivalence with the predicate. We consider our intent to market this device as confidential commercial information and request that it be treated as such by FDA. We have taken precautions to protect the confidentiality of the intent to market these devices. We understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C 331 (q).

1.CD
50

康力得生技股份有限公司
CoreLeader Biotech CO., LTD
22102 新北市汐止區新台五路一段100號19樓

Thank you in advance for your consideration of our application. If there are any questions, please feel free to contact me at the aforementioned contact information.

Sincerely,

Ya-Wen Kuo

Ya-Wen Kuo
Manager, Regulatory Affair
CoreLeader Biotech Co., Ltd

Content

Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER:
b(4) [redacted]
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

CORELEADER BIOTECH CO LTD
19F NO 100 SEC 1 SINTAI 5TH RD SIJHIH CITY TAIPEI 22102

TW

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)

2. CONTACT NAME
YaWen Kuo
2.1 E-MAIL ADDRESS
ywk701@gmail.com
2.2 TELEPHONE NUMBER (include Area code)
886-226968880
2.3 FACSIMILE (FAX) NUMBER (Include Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[X] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Numbe b(4) [redacted]

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] The sole purpose of the application is to

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

support conditions of use for a pediatric population

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 8455 Colesville Road, COLE-14-14253 Silver Spring, MD 20993-0002

[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

b(4) [redacted] 27-Apr-2015

Form FDA 3601 (05/13)

"Close Window" Print Cover sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
04/28/2015	b(4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Submision Issue Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
CoreLeader Biotech Co., Ltd	3009317711		
Division Name *(if applicable)*	Phone Number *(including area code)*		
	+886-2-26968880		
Street Address	FAX Number *(including area code)*		
19F, Build. B, No.100, Sec. 1, Xintai 5th Rd., Xizhi Dist.	+886-2-26968882		
City	State / Province	ZIP/Postal Code	Country
New Taipei City		221	Taiwan (R.O.C)
Contact Name			
Ya-Wen Kuo			
Contact Title	Contact E-mail Address		
Dr.	ywk701@gmail.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	Phone Number *(including area code)*		
Street Address	FAX Number *(including area code)*		
City	State / Province	ZIP Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

PSC Publishing Services (301) 443-6740 EF

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Response to FDA correspondence:

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify)*:

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	FRO	2	FRO	3	FRO	4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached

☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K080818	1	HemCon Chitoflex surgical wound dressing	1	HemCon Medical Technologies, Inc
2	K123387	2	QuikClot® Combat Gauze	2	Z-Medica, LLC
3	K113560	3	Celox Gauze PRO	3	Medtrade Product Ltd
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

CoreLeader HEMO-Bandage

	Trade or Proprietary or Model Name for This Device		Model Number
1	HEMO-Bandage	1	CF-W
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 K141198	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☒ Laboratory Testing ☒ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
FRO	Part 21 CFR 801 Subpart D	☐ Class I ☐ Class II ☐ Class III ☒ Unclassified

Classification Panel

General & Plastic Surgery

Indications *(from labeling)*

CoreLeader HEMO-Bandage is intended to be used as a topical dressing to temporarily control moderate to severe external bleeding resulted from traumatic or surgical wounds

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number: 3009317711	☒ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler

Company / Institution Name	Establishment Registration Number
CoreLeader Biotech Co., Ltd	3009317711
Division Name *(if applicable)*	Phone Number *(including area code)*: +886-2-26968880
Street Address: 19F, Build. B, No.100, Sec. 1, Xintai 5th Rd	FAX Number *(including area code)*: +886-2-26968882

City	State / Province	ZIP Code	Country
New Taipei City		221	Taiwan (R.O.C)

Contact Name	Contact Title	Contact E-mail Address
Teeming Tsao	CEO	tsaotm.coreleader@gmail.com

☐ Original ☒ Add ☐ Delete	Facility Establishment Identifier (FEI) Number: b(4)	☐ Manufacturer ☐ Contract Manufacturer ☒ Contract Sterilizer ☐ Repackager / Relabeler

Company / Institution Name	Establishment Registration Number
b(4)	b(4)
Division Name *(if applicable)*	Phone Number *(including area code)*: b(4)
Street Address: b(4)	FAX Number *(including area code)*: b(4)

City	State / Province	ZIP Code	Country
b(4)		b(4)	b(4)

Contact Name	Contact Title	Contact E-mail Address
b(4)	b(4)	b(4)

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler

Company / Institution Name	Establishment Registration Number
Division Name *(if applicable)*	Phone Number *(including area code)*
Street Address	FAX Number *(including area code)*

City	State / Province	ZIP Code	Country

Contact Name	Contact Title	Contact E-mail Address

SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
	Standards No.	Standards Organization	Standards Title	Version	Date
1	ISO 14971	ISO	Medical devices -- Application of risk management to medical devices	2007	11/02/2010
2	AAMI/ANSI/ISO 11137-1, -2	AAMI/ANSI/ISO	Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices Part 2: Establishing the sterilization dose	2006	12/23/2005
3	ANSI/AAMI/ISO 11737-1, 11737-2	ANSI/AAMI/ISO	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products. Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterility process.	2006	03/23/2006
4	ASTM F1980	ASTM	Standard guide for accelerated aging of sterile medical device packages	07	04/01/2007
5	ISO 10993-5	ISO	Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity	2009	06/18/2009
6	ISO 10993-10	ISO	Biological evaluation of medical devices Part 10: Tests for irritation and delayed-type hypersensitivity	2010	09/04/2010
7	ISO 10993-11	ISO	Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity	2006	03/28/2006

Please include any additional standards to be cited on a separate page.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

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SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
	Standards No.	Standards Organization	Standards Title	Version	Date
1	USP<85>	The United States Pharmacopeial Convention	BACTERIAL ENDOTOXINS Standard Endotoxin Stock Solution	2011	04/01/2011
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 14971: Medical devices--Applications of risk management to medical devices

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-40	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IISO 14971: Medical devices--Applications of risk management to medical devices

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	Risk Analysis	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Use FMEA model to analysis hazard level before and after risk reduction

DESCRIPTION
The hazards of HEMO-Bandage are identified and reduced.

JUSTIFICATION
All identified risks of HEMO-Bandage are reduced to the acceptive level.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI ANSI ISO 11137-1:2006/(R) 2010, Sterilization of health care products - Radiation

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-297	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
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Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
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Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
AAMI ANSI ISO 11137-1:2006/(R) 2010, Sterilization of health care products - Radiation

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8	Process definition	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION Ensure the safety of radiation process and sterilization result.		
JUSTIFICATION HEMO-bandage is suitable for gamma-radiation.		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI / ANSI / ISO 11137-2:2012,Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose.

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-364	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

AAMI / ANSI / ISO 11137-2:2012,Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose.

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Dose setting using bioburden information	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

Determine the gamma radiation dose for HEMO-bandage.

JUSTIFICATION

HEMO-bandage is sterilized with 25 kGy gamma radiation.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F1980-07:Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-229	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
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Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ASTM F1980-07, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Accelerated aging plan	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION
Assess shelf-life of HEMO-bandage

JUSTIFICATION
The shelf-life of HEMO-bandage is determined to be 3 years.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7.4	Maximization test for delayed hypersensitivy	☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION
Assess dermal sensitivity on guinea pigs after treated with HEMO-bandage extraction.

JUSTIFICATION
HEMO-bandage does not cause dermal sensitivity.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI / ANSI / ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity.

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-153	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
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Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
AAMI / ANSI / ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity.

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.2	Tests for in vitro cytotoxicity	☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION
HEMO-bandage did not raise cytotoxicity signs.

JUSTIFICATION
HEMO-bandage is not cytotoxic.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI ANSI ISO 10993-10:2010:Tests for irritation and delayed-type hypersensitivity

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-152	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
AAMI ANSI ISO 10993-10:2010:Tests for irritation and delayed-type hypersensitivity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6.3	Irritation tests	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION
Assess dermal irritation on rabbits after treated with HEMO-bandage extraction

JUSTIFICATION
HEMO-bandage does not cause dermal irritation.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7.4	Maximization test for delayed hypersensitivy	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION
Assess dermal sensitivity on guinea pigs after treated with HEMO-bandage extraction.

JUSTIFICATION
HEMO-bandage does not cause dermal sensitivity.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-11: Biological evaluation of medical devices part 11: Tests for systemic toxicity

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-176	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
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Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
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If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 10993-11

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	Tests for systemic toxicity	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Intravenous and Intraperitoneal acute systemic test

DESCRIPTION
HEMO-Bandage is tested for these two scenario.

JUSTIFICATION
HEMO-Bandage is proved not inducing systemic reactions

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

USP <85> Bacterial endotoxins test. (Sterility)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-442	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
USP <85> Bacterial endotoxins test. (Sterility)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
85	Bacterial endotoxins test	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
LAL test is used.

DESCRIPTION
The acceptance criteria is < 0.5 EU/ml

JUSTIFICATION
HEMO-Bandage fulfills the criteria.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Chapter 3

510(k) Cover Letter

康力得生技股份有限公司
CoreLeader Biotech CO., LTD
22102 新北市汐止區新台五路一段100號19樓

Date: 9th April 2015
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center WO66-G609
10903 New Hampshire Avenue, Silver Spring, Maryland 20993-0002

Traditional 510(k): New Device Submission

Device Name:	CoreLeader HEMO-Bandage
Common Name:	Topical wound dressing
K Number:	unknown
Class	Unclassified
Panel	General & Plastic Surgery
510(k) Submitter:	CoreLeader Biotech Co., Ltd. 19F, No. 100, Sec. 1, Xintai 5th Rd., Xizhi Dist., New Taipei City, Taiwan, R.O.C. 22102 Phone: +886-2-26968880 Fax: +886-2-26968882
Contact Person:	Ya-Wen Kuo Manager, Regulatory Affair 19F, No. 100, Sec. 1, Xintai 5th Rd., Xizhi Dist., New Taipei City, Taiwan, R.O.C. 22102 Phone: +886-2-26968880 FAX: +886-2-26968882 E-mail: ywk@coreleaderbio.com
eCopy Statement:	The eCopy is an exact duplicate of the paper copy.

康力得生技股份有限公司
CoreLeader Biotech CO., LTD
22102 新北市汐止區新台五路一段100號19樓

To whom it may concern,

Coreleader Biotech Co., Ltd hereby submits this Traditional 510(k): New Device to get substantial equivalence clearance for our new product CoreLeader HEMO-Bandage before marketing. This new device functions to manage moderate to severe bleedings resulted from traumatic wounds and reduce risk of wound infection as well. We believe CoreLeader HEMO-Bandage is of the similar safety and efficacy as the predicate devices since they have the same fundamental technologies and mode of actions.

This is (b) (4) submission of this medical device. The K-number of the previous submission is b(4)

The required information is briefed as follows,

1. ***The in vivo animal study lacks supportive data which show b(4) devices.***
2. ***The source of chitosan and manufacturing process used for the device are not clearly identified.***
3. ***Revise Indications for Statement to clearly b(4)***
4. ***Provide the reasoning for b(4) for the measurement parameters in bench test.***
5. ***Please provide a b(4) l and b(4) from positive control testing completed within b(4) for the b(4)***
6. ***Please provide the information regarding to the b(4)***
7. ***Please provide evidence showing the medical device will not b(4)***
8. ***Please provide the results of b(4)***
9. ***Please indicate the b(4) in the device on the label.***

We incorporate the required data into each related chapter of this submission to present the complete evidence of substantial equivalence with the predicate. We consider our intent to market this device as confidential commercial information and request that it be treated as such by FDA. We have taken precautions to protect the confidentiality of the intent to market these devices. We understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C 331 (q).

康力得生技股份有限公司
CoreLeader Biotech CO., LTD
22102 新北市汐止區新台五路一段100號19樓

Thank you in advance for your consideration of our application. If there are any questions, please feel free to contact me at the aforementioned contact information.

Sincerely,

Ya-Wen Kuo

Ya-Wen Kuo
Manager, Regulatory Affair
CoreLeader Biotech Co., Ltd

Table 3 Design and Use of the Device

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)? [A]	YES	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?[A]		NO
Does the device contain components derived from a tissue or other biologic source?	YES	
Is the device provided sterile?	YES	
Is the device intended for single use?	YES	
Is the device a reprocessed single use device?		NO
If yes, does this device type require reprocessed validation data?		NO
Does the device contain a drug?		NO
Does the device contain a biologic?		NO
Does the device use software?		NO
Does the submission include clinical information?		NO
Is the device implanted?		NO

[A]: A device may be intended for both prescription and over-the-counter use. If so, the answer to both of these questions is yes.

Chapter 4

Indications for Use Statement

Indications for Use Statement

510(k) Number (if known):

Device Name: CoreLeader HEMO-Bandage

Indications for Use:

CoreLeader HEMO-Bandage is intended to be used as a topical dressing to temporarily control moderate to severe external bleeding resulted from traumatic or surgical wounds.

Prescription Use __X__ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

_____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Chapter 5

510(k) Summery

510(k) Summary

Submitted by:	Coreleader Biotech Co., Ltd. 19F, No. 100, Sec. 1, Xintai 5th Rd., Xizhi Dist., New Taipei City, Taiwan, R.O.C. 22102 Phone: +886-2-26968880 FAX: +886-2-26968882
Contact Person:	Ya-Wen Kuo
Date Prepared:	2014/03/19
Proprietary Name:	CoreLeader HEMO-Bandage
Common Name:	Topical hemostasis wound dressing
Classification:	Unclassified
Classification Name:	Dressing, Wound, Drug
Predicate Device:	1. HemCon Chitoflex surgical wound dressing (HemCon Medical Technologies, Inc): K080818 2. QuikClot® Hemostatic Dressing, as known as QuikClot® Combat Gauze (Z-Medica, LLC): K123387 3. Celox Gauze PRO/OTC (Medtrade Products Ltd): K113560

Device Description:

CoreLeader HEMO-Bandage is woven gauze made of chitosan fiber and rayon fiber. Chitosan is a type of organic polysaccharide carrying positively-charged ions. Appearing light yellow color and inheriting biodegradability and biocompatibility of chitosan, CoreLeader HEMO-Bandage achieves hemostasis by attracting erythrocytes to the injured sites and facilitates blood clot formation. CoreLeader HEMO-Bandage is sterilized by gamma-ray radiation to 10^{-6} SAL after packed in a foil bag. With the softness and flexibility, it is readily conformable to various wound shapes.

Indications for Use:

CoreLeader HEMO-Bandage is intended to be used as a topical dressing to temporarily control moderate to severe external bleeding resulted from traumatic or surgical wounds.

Substantial equivalence:

The safety and efficacy of CoreLeader HEMO-Bandage wound dressing are substantially equivalent to the predicate devices, including HemCon Chitoflex surgical wound dressing (HemCon Medical Technologies, Inc, K080818) and QuikClot® Hemostatic Dressing, as known as QuikClot® Combat Gauze (Z-Medica, LLC, K123387), in the aspect of the mode of action, dressing form, indications for use,

biocompatibility, sterilization degree and hemostasis efficacy.

1 **Indications for use:** Similar to HemCon Chitoflex surgical wound dressing and QuikClot® Combat Gauze, CoreLeader HEMO-Bandage is intended to be used as a topical dressing to temporarily control moderate to severe external bleeding resulted from traumatic or surgical wounds.

2 **Mode of action in hemostasis:**
Similar to HemCon Chitoflex and Celox Gauze, the effective ingredient of CoreLeader HEMO-Bandage that helps stop bleeding is chitosan, which facilitates hemostatic activity by ion electrostatic bonding mechanism.

3 **Form:**
Similar to HemCon Chitoflex surgical wound dressing and QuikClot® Combat Gauze, CoreLeader HEMO-Bandage appears as flat sheet of gauze with various sizes to fit in different shape of wounds.

4 **Materials:**
Chitosan: Similar to HemCon Chitoflex surgical wound dressing, CoreLeader HEMO-Bandage uses unique ion electrostatic properties of chitosan to facilitate hemostasis activity.
Rayon: Similar to HemCon Chitoflex surgical wound dressing and QuikClot® Combat Gauze, CoreLeader HEMO-Bandage incorporates a textile in addition to effective ingredient to form the gauze dressing..

5 **Non-clinical tests**

6.1 Sterility: Similar to HemCon Chitoflex surgical wound dressing and QuikClot® Combat Gauze, CoreLeader HEMO-Bandage is sterilized to 10^{-6} SAL using gamma ray. The sterilization validation tests meet the criteria of AAMI / ANSI / ISO 11137-1, -2: 2006.

6.2 Shelf life: The shelf life of CoreLeader HEMO-Bandage is 3 years when the product is stored at room temperature without sun light exposure. The shelf life of HemCon Chitoflex surgical wound dressing is 2 years, while QuikClot® Combat Gauze is 3 years.

6.3 Biocompatibility: CoreLeader HEMO-Bandage is as biocompatible as all the predicates.

6.3.1 Cytotoxicity: CoreLeader HEMO-Bandage passes *in vitro* cytotoxicity test required in AAMI / ANSI / ISO 10993-5.

6.3.2 Skin irritation test: CoreLeader HEMO-Bandage passes *in vivo* rabbit skin irritation test required in AAMI / ANSI / ISO 10993-10.

6.3.3 Skin sensitization: CoreLeader HEMO-Bandage passes *in vivo* guinea pig skin sensitization test required in AAMI / ANSI / ISO 10993-10.

6.4 Performance:

6.4.1 Water absorption: As the above mentioned predicate devices, CoreLeader HEMO-Bandage is fluid absorbent.

6.4.2 Hemostasis achievement: CoreLeader HEMO-Bandage is capable of stop bleeding due to the nature of chitosan. CoreLeader HEMO-Bandage is proved to achieve arterial hemostasis in *in vivo* swine femoral arterial hemorrhage model.

7 Directions to use: The direction of use of CoreLeader HEMO-Bandage is similar to those of HemCon Chitoflex surgical wound dressing and QuikClot® Combat Gauze. CoreLeader HEMO-Bandage should be directly packed or pressed against the bleeding wounds until the hemostasis is achieved. Proper saline irrigation should be applied when removing CoreLeader HEMO-Bandage from the wound.

Table 1. The list of non-clinical tests conducted to validate the safety and efficacy of CoreLeader HEMO-Bandage to achieve the indications as claimed.

Test	Result	Guidance
Sterilization validation tests	CoreLeader HEMO-Bandage is sterile to 10^{-6} SAL after gamma radiation.	AAMI / ANSI / ISO 11137-1, -2: 2006
Shelf life test	CoreLeader HEMO-Bandage is expired 3 years after manufacturing.	ASTM F1980-07
In vitro cytotoxicity test	No cytotoxicity	AAMI / ANSI / ISO 10993-5:2009
In vivo guinea pig skin sensitization test	No skin sensitization	AAMI / ANSI / ISO 10993-10: 2010.
In vivo rabbit skin irritation	No skin irritation	AAMI / ANSI / ISO

test		10993-10: 2010.
In vivo systemic toxicity test	Non-systemic toxic	AAMI / ANSI / ISO 10993-11: 2006.
Heavy metal residue test	Free of heavy metal contamination	Journal of AOAC International, 2006; 89(6): 1447-66
Fluid absorption rate	CoreLeader HEMO-Bandage is water absorbent.	EN 13726-1:2002 —Part 1
Tensile strength	CoreLeader HEMO-Bandage is tensile resistant.	In-house protocol
In vivo hemostasis test	CoreLeader HEMO-Bandage can temporarily control moderate to severe bleedings resulted from traumatic or surgical wounds.	In-house protocol

Table 2. A comparison of non-clinical testing results of CoreLeader HEMO-Bandage with the predicate devices

	Proposed device	Predicate device		
	CoreLeader HEMO-Bandage	HemCon® Chitoflex	CELOX Gauze PRO	QuikClot® Combat Gauze
K number	K141198	K0808018	K113560	K123387
Indications	CoreLeader HEMO-Bandage is intended to be used as a topical dressing to temporarily control moderate to severe bleeding resulted from traumatic or surgical wounds.	QuikClot® Combat Gauze is intended to use as a topical dressing for local management of bleeding wounds such as cuts, lacerations and abrasions. It may also be used for temporary treatment of severely bleeding wounds such as surgical wounds (operative, postoperative, dermatological, etc.) and traumatic injuries.	CELOX Gauze PRO is indicated for minor wound control, including control of minor external bleeding and exudate from sutures and/or surgical procedures	Rx indication: Hemostatic dressing for temporary control of severely bleeding wounds intended for emergency use.

Mode of action	Electrostasis nature of chitosan	Electrostasis nature of chitosan	Electrostasis nature of chitosan	Electrostasis nature of kaolin
Sterilization	Gamma radiation to 10^{-6} SAL	Gamma radiation	Gamma radiation	Gamma radiation
Shelf life	3 years	2 years	3 years	3 years
Cytotoxicity test	Negative	Negative	Negative	Negative
Skin irritation test	Negative	Negative	Negative	Negative
Skin sensitization test	Negative	Negative	Negative	Negative
*S*ystemic toxicity tes*t*	Negative	Negative	Negative	Negative
In vivo swine hemostasis test	Achieve hemostasis of femoral artery hemorrhage < 10 minutes.	Facilitate hemostasis	Facilitate hemostasis	Facilitate hemostasis

Substantial Equivalent Statement

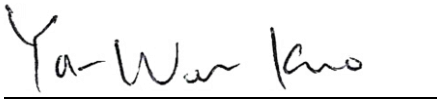
Based on the comparison of intended use, design, mode of actions, and performance, CoreLeader HEMO-Bandage is substantial equivalent to its predicate devices.

Chapter 6

Truthful and Accurate Statement

Truthful and Accurate Statement

I certify that, in my capacity as a manager of Regulatory Affair of CoreLeader Biotech Co., Ltd, I believe, to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



Ya-Wen Kuo
Manager, Regulatory Affair
CoreLeader Biotech Co., Ltd

Ya-Wen Kuo
Typed Name

2015/04/28
Date

_____
*(Premarket Notification [510(k)] Number)

*For a new submission, leave the 510(k) number blank.

Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not a consultant for the 510(k) submitter].

Chapter 7
Class III Summary and Certification

(Not Applicable)

Chapter 8
Financial Certification or Disclosure Statement

(Not Applicable)

Chapter 9
Declaration of Conformity and Summery Report
(Not applicable)

Chapter 10

Executive Summery

Executive Summary

1. Device description

Coreleader HEMO-Bandage is woven gauze made of chitosan fiber b(4) . Chitosan is a type of organic polysaccharide carrying positively-charged ions. Appearing light yellow color and inheriting biodegradability and biocompatibility of chitosan, Coreleader HEMO-Bandage achieves hemostasis by attracting platelets and erythrocyte to the injured sites and facilitates blood clot formation. b(4) It is a kind of b(4) and encompasses biocompatibility and biodegradability. b(4) b(4) . Coreleader HEMO-Bandage is readily conformable to various wound shapes. In addition, Coreleader HEMO-Bandage is capable to resist bacterial growth due to the electrostasis nature of chitosan, hence reducing the risk of wound infection.

2. Indications for use

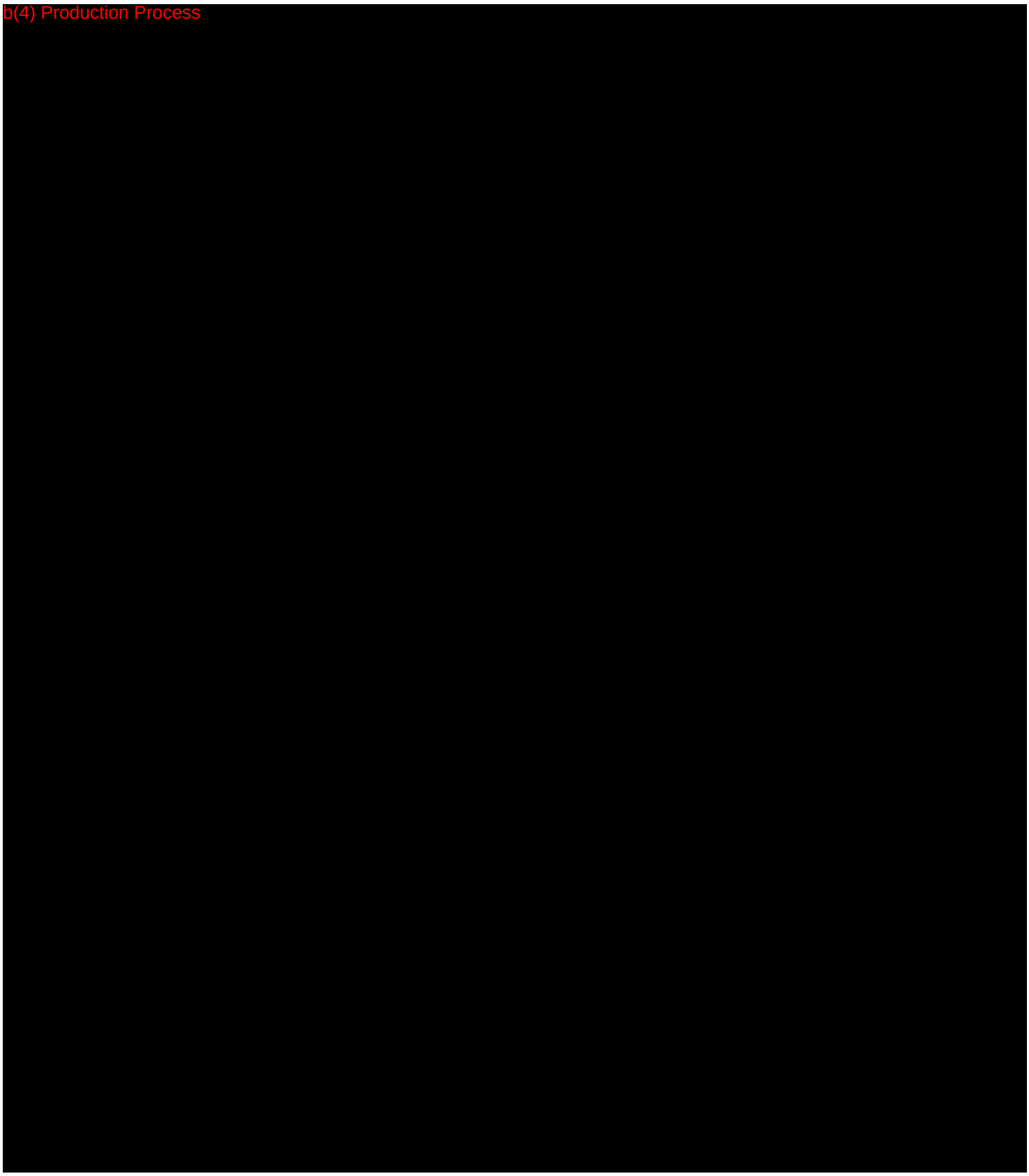
Coreleader HEMO-Bandage is intended to be used as a topical dressing to temporarily control moderate to severe external bleeding resulted from traumatic or surgical wounds.

3. Mode of Action

Coreleader HEMO-bandage is woven gauze made of chitosan fiber b(4) Chitosan is an organic polysaccharide carrying cations (positively charged ions), which attracts negatively charged particles in blood, i.e. erythrocytes, to the wound sites and form strong blood clots. The blood clots aggregating on the open wound result in hemostasis. Chitosan also has antibacterial property, which is found to be antimicrobial for certain bacterial strains. Being manufactured from natural substance, chitosan wound dressing is biocompatible and biodegradable. The features of chitosan mentioned above are widely reported in scientific journal papers. b(4)

4. Manufacturing Technology

b(4) Production Process



12.	Sterilization	CoreLeader HEMO-Bandage is sterilized by gamma-ray radiation in a contracted facility.
13.	Physical property test	1. Base weight 2. Tensile strength test 3. Fluid absorption rate

5. Non-clinical tests

5.1 Sterility: CoreLeader HEMO-Bandage is sterilized to [redacted] using gamma ray. The sterilization validation tests meet the criteria of AAMI / ANSI / ISO 11137-1, -2: 2006.

5.2 Shelf life: The shelf life of CoreLeader HEMO-Bandage is 3 years when the product is stored at room temperature without sun light exposure. The shelf life study used accelerated aging protocols in ASTM F1980-07: Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices. The results showed that fibrous structure and sterile condition of Coreleader HEMO-bandage are similar to those of fresh product after heated for [redacted] These heating durations simulate 1-year, 2-year, and 3-year storage time, respectively.

5.3 Biocompatibility:

5.3.1 Cytotoxicity: Coreleader HEMO-bandage passes *in vitro* cytotoxicity test required in AAMI / ANSI / ISO 10993-5:2009: Biological evaluation of medical devices－part 5: Test for in vitro cytotoxicity guidelines.

5.3.2 Skin irritation test: Coreleader HEMO-bandage passes *in vivo* rabbit skin irritation test required in AAMI / ANSI / ISO 10993-10: 2010: Biological evaluation of medical devices－part 10: Tests for irritation and skin sensitization.

5.3.3 Skin sensitization: Coreleader HEMO-bandage passes *in vivo* guinea pig skin sensitization test required in AAMI / ANSI / ISO 10993-10: 2010: Biological evaluation of medical devices－part 10: Tests for irritation and skin sensitization.

5.3.4 Acute Systemic toxicity: Coreleader HEMO-bandage passes *in vivo* acute intraperitoneal and intravenous systemic toxicity test required in

AAMI / ANSI / ISO 10993-11: 2006: Tests for systemic toxicity.

5.4 Heavy metal test: Coreleader HEMO-bandage is free of heavy metal contamination, including arsentic, lead, cadmium, copper, and mercury. The detection method is based on Journal of AOAC International, 2006; 89(6): 1447-66.

5.5 Performance test:

5.5.1 Fluid absorption: Coreleader HEMO-bandage is fluid absorbent, which is tested according to the protocols in EN 13726-1:2002. The fluid absorbency is > 3 times the product weight.

5.5.2 Mechanical strength: Coreleader HEMO-bandage encompasses the strength due to exclusive weaving techniques. The mechanical tensile modulus of Coreleader HEMO-bandage is > (b) (4) in average.

5.5.3 Hemostasis achievement: CoreLeader HEMO-bandage is capable of stop bleeding due to the nature of chitosan. It is proved to achieve arterial hemostasis in swine femoral arterial hemorrhage model. In this *in vivo* study, the femoral arterial was injured by 6-mm diameter punch wound and has bled for (b) (4) before the application of the product. The initial hemostasis was achieved in about (b) (4) within two pieces of application. The swine survived in (b) (4) after initial hemostasis achievement. This in vivo test backs up the indications of CoreLeader HEMO-Bandage in facilitating hemostasis for traumatic wounds.

6. Substantial equivalence

Three predicate devices with 510(k) clearance are proposed to compare with Coreleader HEMO-bandage:

- QuikClot® Hemostatic Dressing, as known as QuikClot® Combat Gauze (Z-Medica, LLC): K123387
- HemCon Chitoflex surgical wound dressing (HemCon Medical Technologies, Inc): K080818
- Celox Gauze PRO/Celox Gauze PRO OTC (Medtrade Product Ltd.): K113560

CoreLeader HEMO-Bandage is substantially equivalence to HemCon Chitoflex, Celox

Gauze, and QuikClot® Combat Gauze for their indications to use, sterility condition, shelf-life, and biocompatibility. Coreleader HEMO-bandage contains chitosan and thus shares the common mode of action with HemCon Chitoflex and Celox Gauze. Chitosan carries positively-charged ions, so does kaolin. In other words, Coreleader HEMO-bandage and Comabat Gauze have similar electrostasis characteristic that attract erythrocytes. For the (b) (4) [redacted], HEMO-Bandage is slightly higher than that of Celox Gauze. For the time to achieve hemostasis of femoral arterial injury, HEMO-Bandage is comparable to Combat Gauze.

The substantial equivalences of CoreLeader HEMO-Bandage to the predicate devices are discussed below and listed in Table 2.

Table 2. Substantial equivalence comparison table

Device Name	Coreleader HEMO-bandage	QuikClot® Hemostasis Combat Gauze	HemCon® Chitoflex surgical dressing	Celox Gauze PRO Celox Gauze PRO OTC
Manufacturer	CoreLeader Biotech Co., Ltd	Z-medica, LLC	HemCon Medical Technologies, Inc.	Medtrade Product Ltd.
FDA approval	Under review for 510(k) clearance	K123387, cleared in 2013	K080818, cleared in 2009	K113560
Material	b. Chitosan fiber ([redacted]	1. Kaolin 2. Glycerin USP 3. Gauze	Chitosan-based pliable sponge dressing	Chitosan coated on gauze
Form	Woven chitosan fabric wound dressing	Gauze-like wound dressing	Sheet-like wound dressing	Non-woven chitosan fabric dressing
Mode of action	1. Chitosan: chitosan is a natural biodegradable poly-saccharide characterized by fluid absorbency and bacterial resistance. Cation on chitosan attracts negatively charged platelets and erythrocytes to vessel wound, and thus	1. Quikclot® Hemostatic Wound dressing is medical gauze coated with kaolin through glycerin USP. Kaolin is a mineral that can trigger blood clot in contact	1. Chitosan: HemCon products are fabricated from chitosan. Because chitosan has a positive charge, it attracts red blood cells, which have a negative charge. The red blood cells create a seal over the wound as they are drawn into the bandage,	CELOX Gauze PRO consists of a chitosan hemostatic granules adhered to a non-woven gauze. The product absorbs water of blood. Platelets are concentrated, resulting in activation of platelets. By applying CELOX Gauze PRO surface creates a physical barrier which

	accelerates blood coagulation. 2 (b) (4) [redacted] and (b) (4) [redacted] with strength and blood absorption when packed in the bleeding wound.	blood through electrostatic interaction.	forming a very tight, coherent seal. In addition to providing hemostasis, HemCon products also offer an antibacterial barrier.	controls blood flow through the dressing to stop bleeding and reduce the risk of re-bleeding.
Intended use	Coreleader HEMO-bandage is intended to be used as a topical dressing to temporarily control moderate to severe bleeding resulted from traumatic or surgical wounds. It is resistant to growth of certain bacterial strains, including staphylococcus aureus, escherichia coli and pseudomonas, and hence reduces risk of wound infection.	QuikClot® Combat Gauze is intended to use as a topical dressing for local management of bleeding wounds such as cuts, lacerations and abrasions. It may also be used for temporary treatment of severely bleeding wounds such as surgical wounds (operative, postoperative, dermatological, etc.) and traumatic injuries.	1. OTC indication: HemCon® Bandage OTC is indicated for the local management of bleeding such as laceration and minor bleeding. 2. Rx indication: Hemostatic dressing for temporary control of severely bleeding wounds intended for emergency use. 3. HemCon Chitoflex surgical wound dressingalso controls bleeding in patients following hemodialysis.	1. OTC indication: CELOX Gauze OTC is indicated for use as a temporary topical dressing for minor cuts, minor abrasions, minor lacerations and minor burns. 2. RX(prescription) indication: CELOX Gauze PRO is indicated for minor wound control, including control of minor external bleeding and exudate from sutures and/or surgical procedures. Under the supervision fo professional healthcare, CELOX Gauze PRO is indicated for temporary external treatment for controlling moderate to

<table>
<tr><td></td><td></td><td></td><td></td><td>severe bleeding of external wounds.</td></tr>
<tr><td>Exudates absorption</td><td>Yes, (b) (4) the dry weight of product</td><td>Yes</td><td>Yes</td><td>Yes, about (b) (4) the dry weight of product</td></tr>
<tr><td>Biodegradable</td><td>Yes</td><td>Yes</td><td>Yes</td><td>Yes</td></tr>
<tr><td>Biocompatibility</td><td>Non-cytotoxic, non-irritating, non-sensitizing, non-acute systemic toxic</td><td>Non-cytotoxic, non-irritating, non-sensitizing</td><td>Non-cytotoxic, non-irritating, non-sensitizing</td><td>Yes, in compliance with the requirements of BS EN ISO 10993-1</td></tr>
<tr><td>Hemostasis capacity</td><td>Temporarily control moderate to severe bleeding</td><td>Temporarily control moderate to severe bleeding</td><td>Temporarily control moderate to severe bleeding</td><td>Temporarily control moderate to severe bleeding</td></tr>
<tr><td>Antimicrobial</td><td>Yes</td><td>No</td><td>Yes</td><td>Not reported.</td></tr>
<tr><td>Use</td><td>Single</td><td>Single</td><td>Single</td><td>Single</td></tr>
<tr><td>Models</td><td><table><tr><td></td><td>cm x cm</td><td>cm^2</td></tr><tr><td>1</td><td>7.5 x 90</td><td>675</td></tr><tr><td>2</td><td>7.5 x 300</td><td>2250</td></tr><tr><td>3</td><td>7.5 x 400</td><td>3000</td></tr><tr><td>4</td><td>10 x 20</td><td>200</td></tr><tr><td>5</td><td>10 x 200</td><td>2000</td></tr><tr><td>6</td><td>10 x 300</td><td>3000</td></tr><tr><td>7</td><td>20 x 200</td><td>4000</td></tr><tr><td>8</td><td>15 x 200</td><td>3000</td></tr><tr><td>9</td><td>15 x 300</td><td>4500</td></tr></table></td><td>1. 2" x 2"= 4 $inch^2$ (5 cm x 5 cm = 25 cm^2)
2. 4" x 4"= 4 $inch^2$ (10 cm x 10 cm = 100 cm^2)
3. 2" x 12"= 24 $inch^2$ (5 cm x 30 cm = 150 cm^2)
4. 3" x 36"= 108 $inch^2$ (7.5 cm x 365 cm = 2738 cm^2)
5. 4" x 36"=144 $inch^2$ (10 cm x 365 cm = 3650 cm^2)</td><td>1. 1.5" x 1.5"= 2.25 $inch^2$ (3.75 cm x 3.75 cm = 14 cm^2)
2. 2" x 2" = 4 $inch^2$ (5 cm x 5cm = 25 cm^2)
3. 2" x 4" = 8 $inch^2$ (5 cm x 10 cm = 50 cm^2)
4. 4” x 4”= 16 $inch^2$ (10 cm x 10 cm=100 cm^2)
5. 4” x 72”=288 $inch^2$ (10 cm x 180 cm=1800 cm^2)</td><td>Only 1 base weight: 250 g/m^2
1. 1” x 1” = 1 $inch^2$ (2.54 cm x 2.54 cm = 6.45 cm^2)
2. 3” x 120” = 360 $inch^2$ (7.62 cm x 304.8 cm= 2322.6 cm^2)
1.</td></tr>
<tr><td>Direction to use</td><td>1. Pack the product into</td><td>1. Open package and</td><td>1. Open the bandage.</td><td>2. Tear open CELOX gauze</td></tr>
</table>

	wounds with firm pressure until bleeding stops. If bleeding persists and soaks the product, pack in another CoreLeader Bandage on top of the original one and apply firm pressure until bleeding stops. Do not remove the product after hemostasis. 2. Wrap the product on wound with sterile gauze to maintain pressure on wound. 3. Take the patient to available standard medical treatment as soon as possible. 4. Proper irrigation with normal saline is needed when removing the dressing from wound.	remove Combat Gauze. Keep the empty package. 2. Pack Combat Gauze into wound and use it to apply pressure directly over bleeding source. (More than one Combat Gauze may be required.) 3. Continue to provide pressure for 3 minutes or until bleeding stops 4. Wrap and tie bandage to maintain pressure. Seek medical care immediately. Show Product Removal directions on package to medical personnel. 5. Product Removal: gently remove gauze from wound, and then thoroughly irrigate the wound.	2. Ensure that the non-stick side is up. 3. Apply directly on the source of bleeding. 4. Apply pressure until bleeding is controlled. 5. Backing the bandage with a Kerlix roll or gauze helps ensure uniform pressure. Maintain pressure on the bandage until bleeding is controlled. 6. The bandage can remain in place for up to 48 hours and should be removed with water or saline.	pack. 3. Pack the unraveled CELOX gauze into the wound. 4. Apply firm pressure directly to the wound for 5 minutes. If any bleeding persists, apply directly pressure for an additional 5 min. 5. Wrap and tie CELOX gauze on to the wound with elastic bandage so as to maintain the pressure on bleeding wounds. 6. Discard any gauze that has not been used to pack the wound. 7. Seek Medical Care as soon as possible when dealing with the severely bleeding wound.

Chapter 11

Device Description

1. General description

CoreLeader HEMO-Bandage (Figure 1) is woven gauze made of chitosan (b) (4) (b) With the softness and flexibility, it is readily conformable to various wound shapes. Chitosan is a type of organic polysaccharide carrying positively-charged ions. Appearing light yellow color and inheriting biodegradability and biocompatibility of chitosan, CoreLeader HEMO-Bandage achieves hemostasis by attracting platelets and erythrocyte to the injured sites and facilitates blood clot formation. The whole dressing is packed into the bleeding wounds to achieve hemostasis. CoreLeader HEMO-Bandage is sterilized by gamma-ray radiation to [redacted] after packed in a foil bag.

Figure 1. Appearance of CoreLeader HEMO-Bandage

2. Ingredient

CoreLeader HEMO-Bandage is made of (b) (4) fiber and (b) (4)

3. Indications for use

CoreLeader HEMO-Bandage is intended to be used as a topical dressing to temporarily control moderate to severe external bleeding resulted from traumatic or surgical wounds.

4. Contraindications

CoreLeader HEMO-Bandage should not be used on patients who are allergic to crustacean animals. It should not be used as a surgical implantation.

5. Mode of action

Chitosan: chitosan is an organic polysaccharide carrying cations (positively charged ions), which attracts negatively charged particles in blood, i.e. platelets and erythrocytes, to the wound sites and form strong blood clots. The blood clots aggregating on the open

wound result in hemostasis. This mechanism enables chitosan wound dressing to stop hemorrhage and to be used as a temporal treatment for severely bleeding wounds. Chitosan is able to absorb fluid greater than its weight, and thus can be used as an absorbent wound dressing to manage bloods and exudates. Chitosan further has antibacterial property, which is found to be antimicrobial for certain strains. Being manufactured from natural substance, chitosan wound dressing is biocompatible and biodegradable. The features of chitosan mentioned above are widely reported in scientific journal papers.[1-4]

(b) (4) [redacted]

6. Risk Analysis

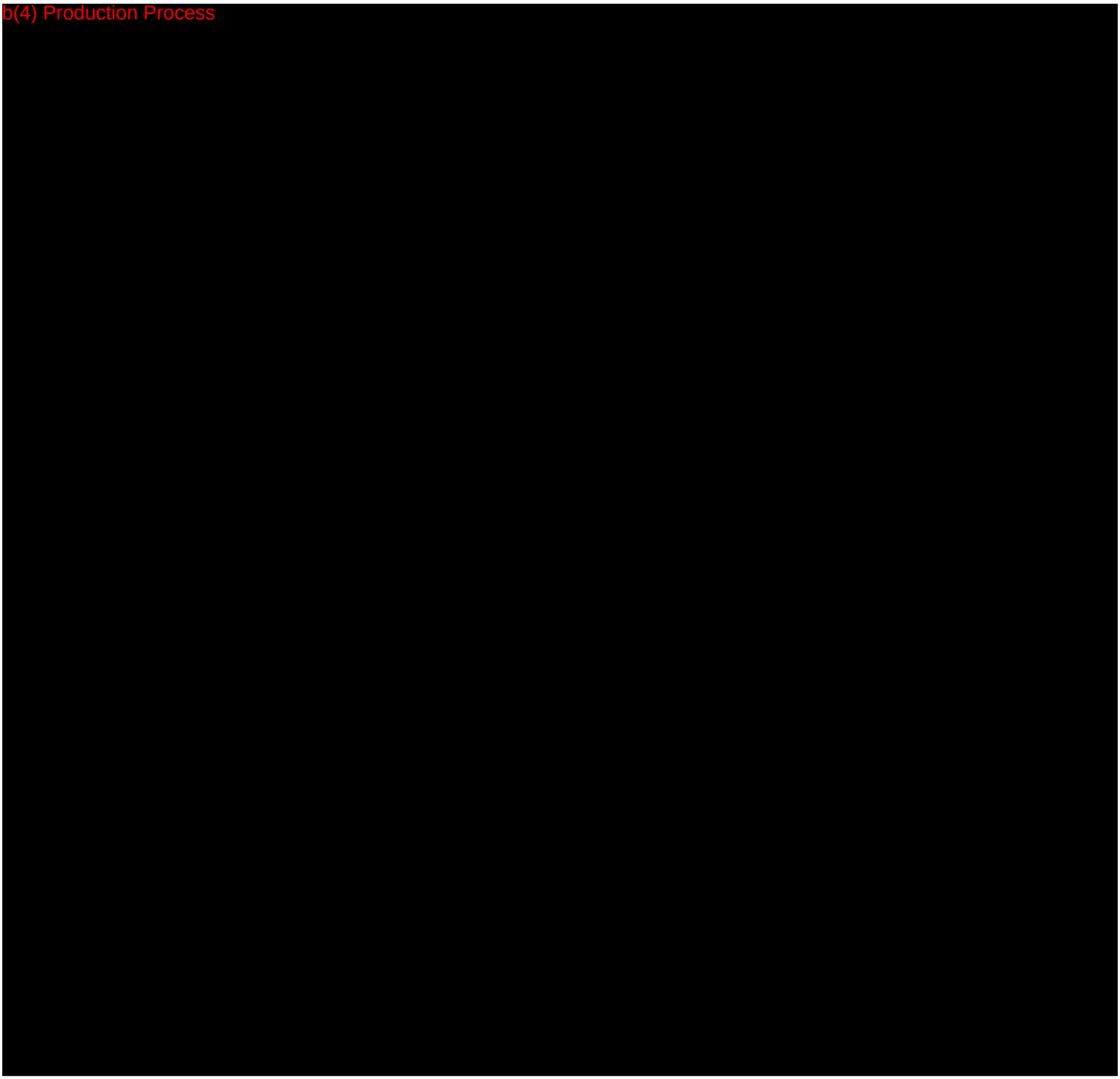
Risk analysis is performed to clarify the safety level of CoreLeader HEMO-Bandage, before design master file creation and product massive manufacturing. Determination of the suitable use of a medical device is related to the risk acceptability, which takes into account the intended use, performance, risks and benefits associated with the clinical practice. This risk analysis is executed by the R&D Department of CoreLeader Biotech Co., Ltd in compliance to ISO14971:2007.

The risk analysis report is listed as Annex 1in the submission.

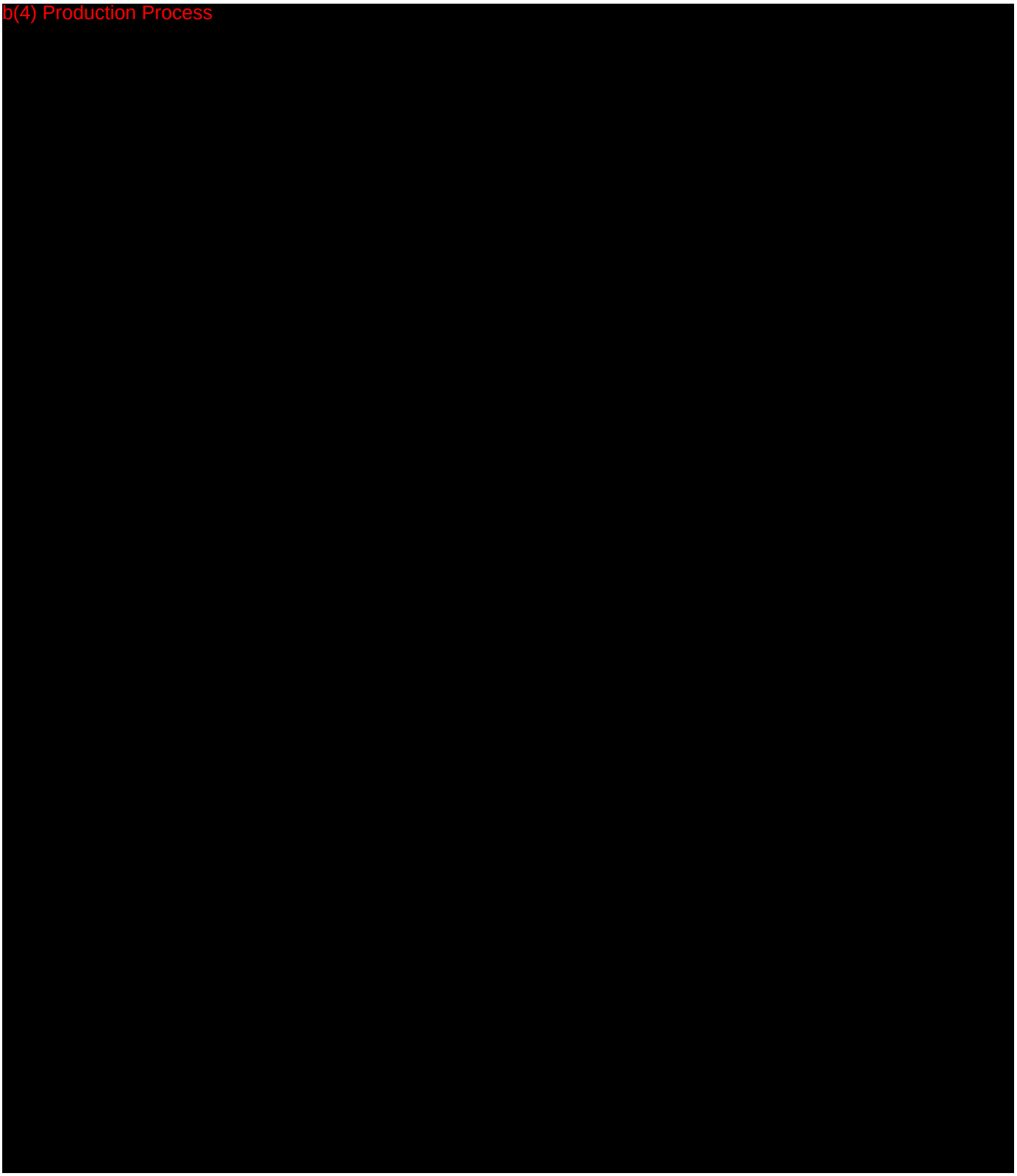
7. Manufacturing Technology

(b) (4) [redacted]

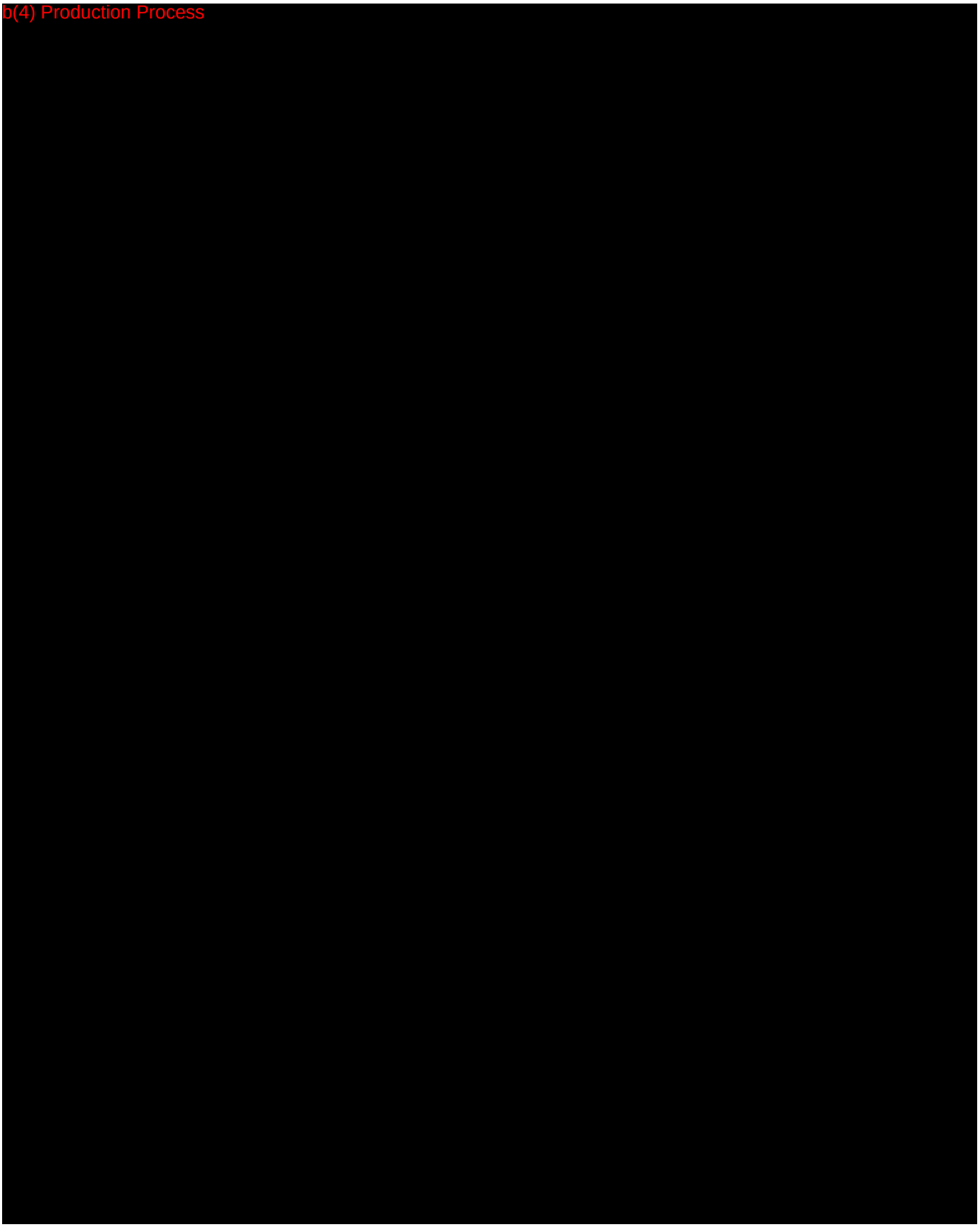
b(4) Production Process



b(4) Production Process



b(4) Production Process



7. Principle of operation

CoreLeader HEMO-Bandage is constituted with chitosan b(4) Production homogenously, and thus any part of it can contact with wound. CoreLeader HEMO-Bandage is for topical use only. To obtain the most optimal efficacy, CoreLeader HEMO-Bandage should be directly pressed against the bleeding wounds. CoreLeader HEMO-Bandage has various sizes to fit in different wound area. If needed, CoreLeader HEMO-Bandage should be packed into bleeding wounds to promote hemostasis. CoreLeader HEMO-Bandage with larger size is capable to absorb more exudates and blood, attracting more erythrocyte and platelets to achieve hemostasis. Therefore, with the severity of bleeding, CoreLeader HEMO-Bandage with broader area should be applied or more than one CoreLeader HEMO-Bandage as needed. In 24 hours, CoreLeader HEMO-Bandage should be removed from the wound and replaced with a fresh one. While replacing or removing the wound dressing, wound should be irrigated with normal saline solution.

References

1. Gustafson SB, Fulkerson P, Bildfell R, et al. Chitosan dressing provides hemostasis in swine femoral arterial injury model. *Prehosp Emerg Care* 2007;11:172-8.

2. Wedmore I, McManus JG, Pusateri AE, et al. A special report on the chitosan-based hemostatic dressing: experience in current combat operations. *J Trauma* 2006;60:655-8.

3. Xie H, Khajanchee YS, Shaffer BS. Chitosan hemostatic dressing for renal parenchymal wound sealing in a porcine model: implications for laparoscopic partial nephrectomy technique. *JSLS* 2008;12:18-24.

4. Xie H, Khajanchee YS, Teach JS, et al. Use of a chitosan-based hemostatic dressing in laparoscopic partial nephrectomy. *J Biomed Mater Res B Appl Biomater* 2008;85:267-71.

Chapter 12

Substantial Equivalence Discussion

Substantial Equivalence

The safety and efficacy of CoreLeader HEMO-Bandage wound dressing are similar to the following predicate devices:

- HemCon Chitoflex surgical wound dressing (HemCon Medical Technologies, Inc): K080818
- QuikClot® Hemostatic Dressing, as known as QuikClot® Combat Gauze (Z-Medica, LLC): K123387
- Celox Gauze PRO/Celox Gauze PRO OTC (Medtrade Product Ltd.): K113560

The substantial equivalences of CoreLeader HEMO-Bandage to the predicate devices are discussed below and listed in Table 1.

1. b(4) [redacted]

2. b(4) [redacted]

b(4) [redacted]

3. b(4) [redacted]

4. b(4) [redacted]

5. b(4) [redacted]

b(4) [redacted].

6. b(4) [redacted]

b(4) [redacted]

7. b(4) [redacted]

b(4) [redacted]

8. b(4) [redacted]

9. b(4) [redacted]

9.1 b(4) [redacted]

10. b(4) [redacted]

Please refer to Ch 19 for detail explanation.

b(4) [redacted]

Table 1. Comparison of "CoreLeader" HEMO-Bandage with predicate devices.

Device Name	CoreLeader HEMO-Bandage	QuikClot® Hemostasis Combat Gauze	HemCon® Chitoflex surgical dressing	Celox Gauze PRO
Manufacturer	CoreLeader Biotech Co., Ltd	Z-medica, LLC	HemCon Medical Technologies, Inc.	Medtrade Product Ltd.
FDA approval	Under review for 510(k) clearance	K123387, cleared in 2013	K080818, cleared in 2009	K113560
Material	1. Chitosan fiber 2. Rayon fiber	1. Kaolin 2. Glycerin USP 3. Gauze	Chitosan-based dressing	Chitosan
Form	Woven chitosan fabric wound dressing	Gauze-like wound dressing	Sheet-like wound dressing	Non-woven chitosan fabric dressing
Mode of action	1. Chitosan: chitosan is a natural biodegradable poly-saccharide characterized by fluid absorbency and bacterial resistance. Cation on chitosan attracts negatively charged platelets and erythrocytes to vessel wound, and thus accelerates blood coagulation. 2. Rayon: rayon is plant cellulose characterized by tensile resistance and fluid absorbency. Rayon provides wound dressing with strength and blood absorption when packed in the bleeding wound.	1. Quikclot® Hemostatic Wound dressing is medical gauze coated with kaolin through glycerin USP. 2. Kaolin is a mineral that can trigger blood clot in contact blood through electrostatic interaction.	1. Chitosan: HemCon products are fabricated from chitosan. Because chitosan has a positive charge, it attracts red blood cells, which have a negative charge. The red blood cells create a seal over the wound as they are drawn into the bandage, forming a very tight, coherent seal. In addition to providing hemostasis, HemCon products also offer an antibacterial barrier.	CELOX Gauze PRO consists of a chitosan hemostatic granules adhered to a non-woven gauze. The product absorbs water of blood. Platelets are concentrated, resulting in activation of platelets. By applying CELOX Gauze PRO surface creates a physical barrier which controls blood flow through the dressing to stop bleeding and reduce the risk of re-bleeding.
Intended use	CoreLeader HEMO-Bandage is intended to be used as a topical dressing to temporarily control moderate to severe external bleeding resulted from traumatic or surgical wounds.	QuikClot® Combat Gauze is intended to use as a topical dressing for local management of bleeding wounds such as cuts, lacerations and abrasions. It may also be used for temporary treatment	1. OTC indication: HemCon® Bandage OTC is indicated for the local management of bleeding such as laceration and minor bleeding. 2. Rx indication: Hemostatic	1. OTC indication: CELOX Gauze OTC is indicated for use as a temporary topical dressing for minor cuts, minor abrasions, minor lacerations and minor burns.

		of severely bleeding wounds such as surgical wounds (operative, postoperative, dermatological, etc.) and traumatic injuries.	dressing for temporary control of severely bleeding wounds intended for emergency use. 3. HemCon Chitoflex surgical wound dressingalso controls bleeding in patients following hemodialysis.	2. RX(prescription) indication: CELOX Gauze PRO is indicated for minor wound control, including control of minor external bleeding and exudate from sutures and/or surgical procedures. Under the supervision of professional healthcare, CELOX Gauze PRO is indicated for temporary external treatment for controlling moderate to severe bleeding of external wounds.
b(4) b(4)	Yes, about b(4) times the product dry weight	b(4	b(4	Yes, b(4)
Biodegradable	Yes	Yes	Yes	Yes
Biocompatibility	Complies with ISO-10993-1	Fulfill ISO 10993-1	Fulfill ISO 10993-1	Fulfill ISO 10993-1
Hemostasis capacity	100% survival rate resulted from 2 sequential 5-min compression using 2 applications of dressings (14g, 10 cm x 150 cm) on *in vivo* 45-sec free bleeding of 6-mm punch injury of femoral arterial of swine model.	33% survival rate resulted from one time of 3-min compression using 1 application of dressings on *in vivo* 45-sec free bleeding of 6-mm punch injury of femoral arterial of swine model.[1]	10% survival rate resulted from 2 sequential 2-min compression using 2 applications of dressings on *in vivo* 45-sec free bleeding of 6-mm punch injury of femoral arterial of swine model.[2]	50% survival rate resulted from one time of 3-min compression using 1 application of dressing (Celox trauma gauze, 19.5g, 7.5 cm x 183 cm) on *in vivo* 45-sec free bleeding of 6-mm punch injury of femoral arterial of swine model.[3]
Use	Single	Single	Single	Single
Models	<table><tr><td></td><td>cm x cm</td><td>cm^2</td></tr><tr><td>1</td><td>7.5 x 90</td><td>675</td></tr><tr><td>2</td><td>7.5 x</td><td>2250</td></tr></table>	1. 2" x 2"= 4 $inch^2$ (5 cm x 5 cm = 25 cm^2) 2. 4" x 4"= 4 $inch^2$	1. 1.5" x 1.5"= 2.25 $inch^2$ (3.75 cm x 3.75 cm = 14 cm^2)	Only 1 base weight: 250 g/m^2 1. 1" x 1" = 1 $inch^2$ (2.54 cm x 2.54

	<table><tr><td></td><td>300</td><td></td></tr><tr><td>3</td><td>7.5 x 400</td><td>3000</td></tr><tr><td>4</td><td>10 x 20</td><td>200</td></tr><tr><td>5</td><td>10 x 200</td><td>2000</td></tr><tr><td>6</td><td>10 x 300</td><td>3000</td></tr><tr><td>7</td><td>20 x 200</td><td>4000</td></tr><tr><td>8</td><td>15 x 200</td><td>3000</td></tr><tr><td>9</td><td>15 x 300</td><td>4500</td></tr></table>	(10 cm x 10 cm = 100 cm^2) 3. 2" x 12"= 24 $inch^2$ (5 cm x 30 cm = 150 cm^2) 4. 3" x 36"= 108 $inch^2$ (7.5 cm x 365 cm = 2738 cm^2) 5. 4" x 36"=144 $inch^2$ (10 cm x 365 cm = 3650 cm^2)	2. 2" x 2" = 4 $inch^2$ (5 cm x 5cm = 25 cm^2) 3. 2" x 4" = 8 $inch^2$ (5 cm x 10 cm = 50 cm^2) 4. 4” x 4”= 16 $inch^2$ (10 cm x 10 cm=100 cm^2) 5. 4” x 72”=288 $inch^2$ (10 cm x 180 cm=1800 cm^2)	cm = 6.45 cm^2) 2. 3” x 120” = 360 $inch^2$ (7.62 cm x 304.8 cm= 2322.6 cm^2)
Direction to use	1. Pack CoreLeader HEMO-Bandage into wounds with firm pressure until bleeding stops. If bleeding persists and soaks the product, pack in another CoreLeader Bandage on top of the original one and apply firm pressure until bleeding stops. Do not remove the product after hemostasis. 2. Wrap CoreLeader HEMO-Bandage on wound with sterile gauze to maintain pressure on wound. 3. Take the patient to available standard medical treatment as soon as possible. 4. Proper irrigation with normal saline is needed when removing the dressing from wound.	1. Pack Combat Gauze into wound and use it to apply pressure directly over bleeding source. (More than one Combat Gauze may be required.) 2. Continue to provide pressure for 3 minutes or until bleeding stops 3. Wrap and tie bandage to maintain pressure. Seek medical care immediately. Show empty package to medical personnel. 4. Gently remove gauze from wound, and then thoroughly irrigate the wound.	1. Open the bandage. 2. Ensure that the non-stick side is up. 3. Apply directly on the source of bleeding. 4. Apply pressure until bleeding is controlled. 5. Backing the bandage with a Kerlix roll or gauze helps ensure uniform pressure. Maintain pressure on the bandage until bleeding is controlled. 6. The bandage can remain in place for up to 48 hours and should be removed with water or saline.	1. Tear open CELOX gauze pack. 2. Pack the unraveled CELOX gauze into the wound. 3. Apply firm pressure directly to the wound for 5 minutes. If any bleeding persists, apply directly pressure for an additional 5 min. 4. Wrap and tie CELOX gauze on to the wound with elastic bandage so as to maintain the pressure on bleeding wounds. 5. Discard any gauze that has not been used to pack the wound. 6. Seek Medical Care as soon as possible when dealing with the severely bleeding wound.

Chapter 13

Proposed Labeling

Proposed Labeling

b(4) Draft Labels

b(4) Draft Labels

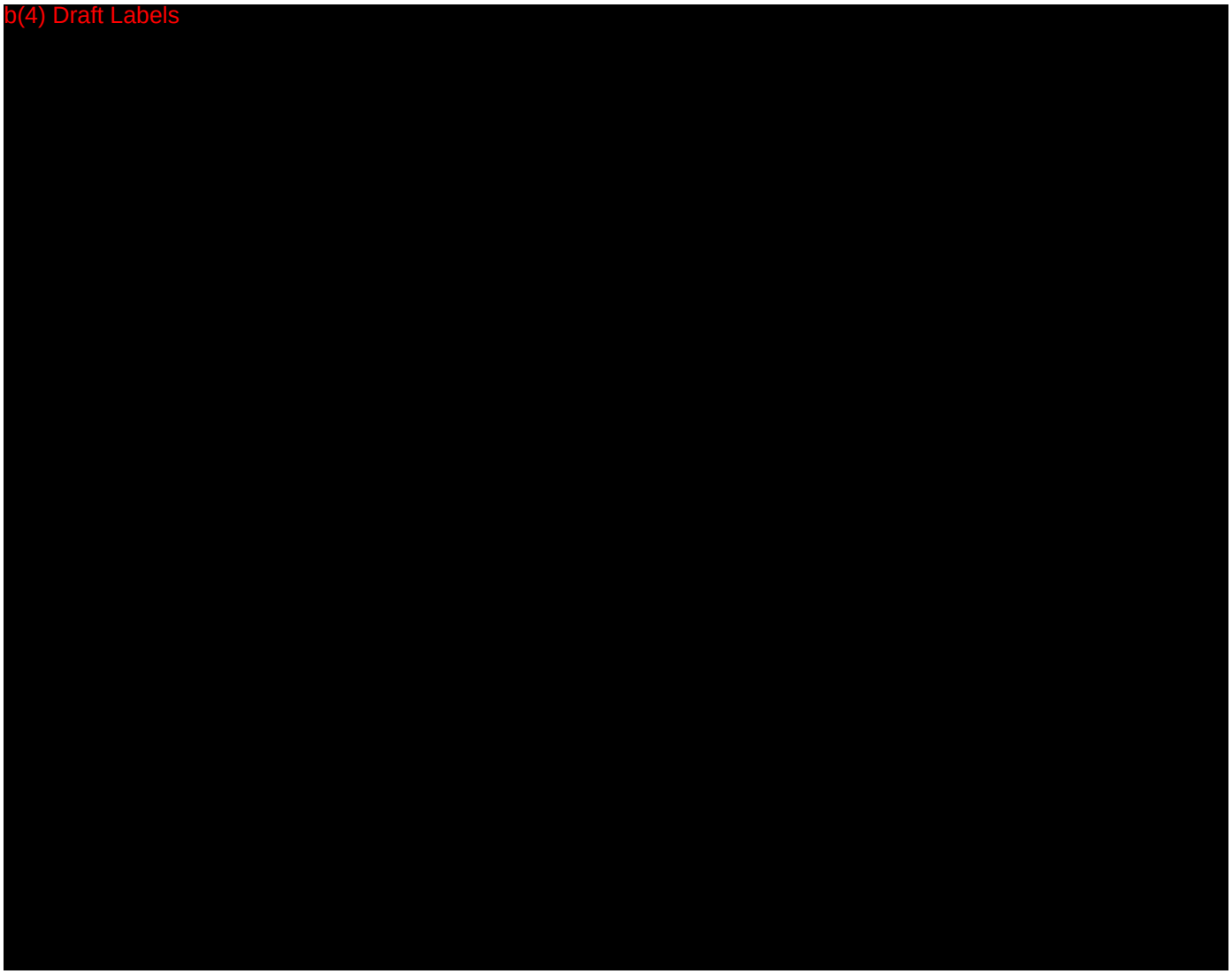


Table 1. The meaning of symbols used in labeling

SYMBOL	MEANING	USAGE	EXAMPLE
	DO NOT REUSE	—	—
	USE BY	Shall be accompanied by the date expressed as four digits for the year and two digits for the month	ex.  1996-06
	BATCH CODE	The batch code shall be adjacent to the symbol. The relative size and location of the symbol and the batch code are not specified.	ex.  061234
	STERILIZATION USING IRRADIATION	Refer EN556	—
	MANUFACTURER	—	—
	CONSULT INSTRUCTION FOR USE	—	—

3. Package insert

1. Description

CoreLeader HEMO-Bandage is woven gauze made of chitosan and b(4) Chitosan is organic polysaccharide carrying positively-charged ions which facilitates blood clot formation through electrostasis property. With the softness and flexibility, it is readily conformable to various wound shapes.

2. Effective Material

Chitosan b(4)

3. Indications for use

CoreLeader HEMO-Bandage is intended to be used as a topical dressing to temporarily control moderate to severe external bleeding resulted from traumatic or surgical wounds.

4. Biocompatibility

CoreLeader HEMO-Bandage passes the tests of cytotoxicity, skin irritation and skin sensitization.

5. Sterility: CoreLeader HEMO-Bandage is sterilized by gamma radiation to reach 10^{-6} SAL.

6. Shelf life: 3 years

7. Directions for Use

[1] Pack CoreLeader HEMO-Bandage into wounds with firm pressure until bleeding stops. If bleeding persists and soaks the product, pack in another CoreLeader Bandage on top of the original one and apply firm pressure until bleeding stops. Do not remove the product after hemostasis.

[2] Wrap CoreLeader HEMO-Bandage on wound with sterile gauze to maintain pressure on wound.

[3] Take the patient to receive standard medical treatment as soon as possible.

[4] Proper irrigation with normal saline is needed when removing the dressing from wound.

8. Storage

The product should be stored at room temperature without sun light exposure.

9. Contraindications

[1] CoreLeader HEMO-Bandage should not be used on patients who are allergic to crustacean animals.

[2] CoreLeader HEMO-Bandage should not be used as a surgical implantation.

10. Warnings and precautions

[1] The product is for single use only. Re-use may cause contamination and weak performance.

[2] The product is sterilized and should not be re-sterilized.

[3] Do not use the product if the package is not intact.

[4] Do not use the product beyond the expiration date.

11. Models.

Model	cm x cm
CF-W075090	7.5 x 90
CF-W075300	7.5 x 300
CF-W075400	7.5 x 400
CF-W100020	10 x 20
CF-W100200	10 x 200
CF-W100300	10 x 300
CF-W200200	20 x 200
CF-W150200	15 x 200
CF-W150300	15 x 300

Manufacturer: CoreLeader Biotech Co., Ltd.

19F., No.100, Sec. 1, Xintai 5th Rd., Xizhi Dist., New Taipei city 221, Taiwan (R.O.C)

Tel : +886-2-2696-8880

Fax : +886-2-2696-8882

Website : www.CoreLeaderbio.com

Issue date: 2015/03/30

Rev.: 1.0

Chapter 14

Sterilization and Shelf Life

Sterilization and Shelf Life

1. **Sterility:** HEMO-Bandage is homogenous woven bandage packed in a foil bag before gamma sterilization.

   CoreLeader HEMO-bandage is sterilized to 10^{-6} SAL using gamma ray with a dose no less than 27.3 kGy. The sterilization validation tests meet the criteria of AAMI / ANSI / ISO 11137-1, -2: 2006: Sterilization of health care product radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices; Part 2: Establishing the sterilization dose.

   The test report is listed as Annex 3.

2. **Shelf life:** The shelf life of CoreLeader HEMO-bandage is 3 years when the product is stored at room temperature without sun light exposure. The shelf life study used accelerated aging protocols in ASTM F1980-07: Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices. The results showed that fibrous structure and sterile condition of CoreLeader HEMO-bandage are similar to those of fresh product after heated for 11, 23, and 34 days at 75℃. These heating durations simulate 1-year, 2-year, and 3-year storage time, respectively.

   The test report is listed as Annex 4.

Chapter 15

Biocompatibility

Biocompatibility

1. **Patient-contacting components:**
   CoreLeader HEMO-bandage is uniformly made of chitosan fiber and rayon fiber. The whole dressing can directly contact the bleeding wounds.

2. **Contact classification:**
   CoreLeader HEMO-bandage should not stay on wounds for longer than 24 hours.

3. **Biocompatibility:** CoreLeader HEMO-bandage passes the biocompatibility tests in accordance with ISO 10993-1.

3.1 Cytotoxicity:

According to ISO 10993-5, the pass/fail criteria are as follows:

- Cell viability ≥ 75%
- Cell morphology grade ≤ 2

CoreLeader HEMO-bandage passes *in vitro* cytotoxicity test required in AAMI / ANSI / ISO 10993-5:2009.

The test report is listed as Annex 5.

For cytotoxicity testing, culture medium with serum was used as vehicle for extraction. At the start of the extraction, the solution appeared clear and free of particulates. After 24 h extraction with constant agitation, the test article medium extract appeared the same original state of the vehicle, clear and free of particulates.

3.2 Skin irritation:

According to ISO 10993-10, the pass/fail criteria are as follows:

- No skin reactions or death in the treatment and corresponding control groups
- The PII values for the tested groups range from 0 to 0.4.

CoreLeader HEMO-bandage passes *in vivo* rabbit skin irritation test required in AAMI / ANSI / ISO 10993-10: 2010.

The test report is listed as Annex 6.

3.3 Skin sensitization:

According to ISO 10993-10, the pass/fail criteria are as follows:

b(4)Validation Procedures

[redacted]

All the extracts were used immediately and directly without any adjustments. For sensitization testing, extracts were maintained at room temperature during extracts-adjuvant preparation, and used within 2 h of preparation.

3.4 Acute intravenous/ intraperitoneal systemic toxicity:

According to ISO 10993-11, the pass/fail criteria are as follows:

- Clinical observation: no abnormal clinical signs were observed in both control and treated mice.
- Mortality: None of the animals in either the control or treatment group died.
- Body weight: No body weight loss > 10% was observed in either the control or treatment group.
- Gross observation: No gross lesions were found in the either the control or treatment group.

CoreLeader HEMO-bandage passes acute intravenous systemic toxicity test required in AAMI / ANSI / ISO 10993-11: 2006.

The test report is listed as Annex 8 (**intravenous)** and Annex 9 (**intraperitoneal)**.

3.5 Endotoxin test:

The pass/fail criteria is < 0.5 EU/ml

The endotoxin level of CoreLeader HEMO-bandage is b(4) [redacted] in the study following USP <85> “Bacterial Endotoxin Test”.

The test report is listed as Annex 10.

3.6 Heavy metal test:

The pass/fail criteria are as follows,

- Lead (pb) b(4) [redacted]
- Cadmium (Cd) b(4) [redacted]
- Mercury (Hg) b(4) [redacted]
- Copper (Cu) b(4) [redacted]
- Arsenic (As) b(4) [redacted]

CoreLeader HEMO-Bandage passes the heavy metal content tests, which proves

that HEMO-Bandage is free of heavy metal contamination, including arsentic, lead, cadmium, copper, and mercury. The testing protocol follows the guidance of detection instrument, Inductively Coupled Plasma-Mass Spectrometer (ICP-MS).

The test report is listed as Annex 11.

Chapter 16
Software

(Not applicable)

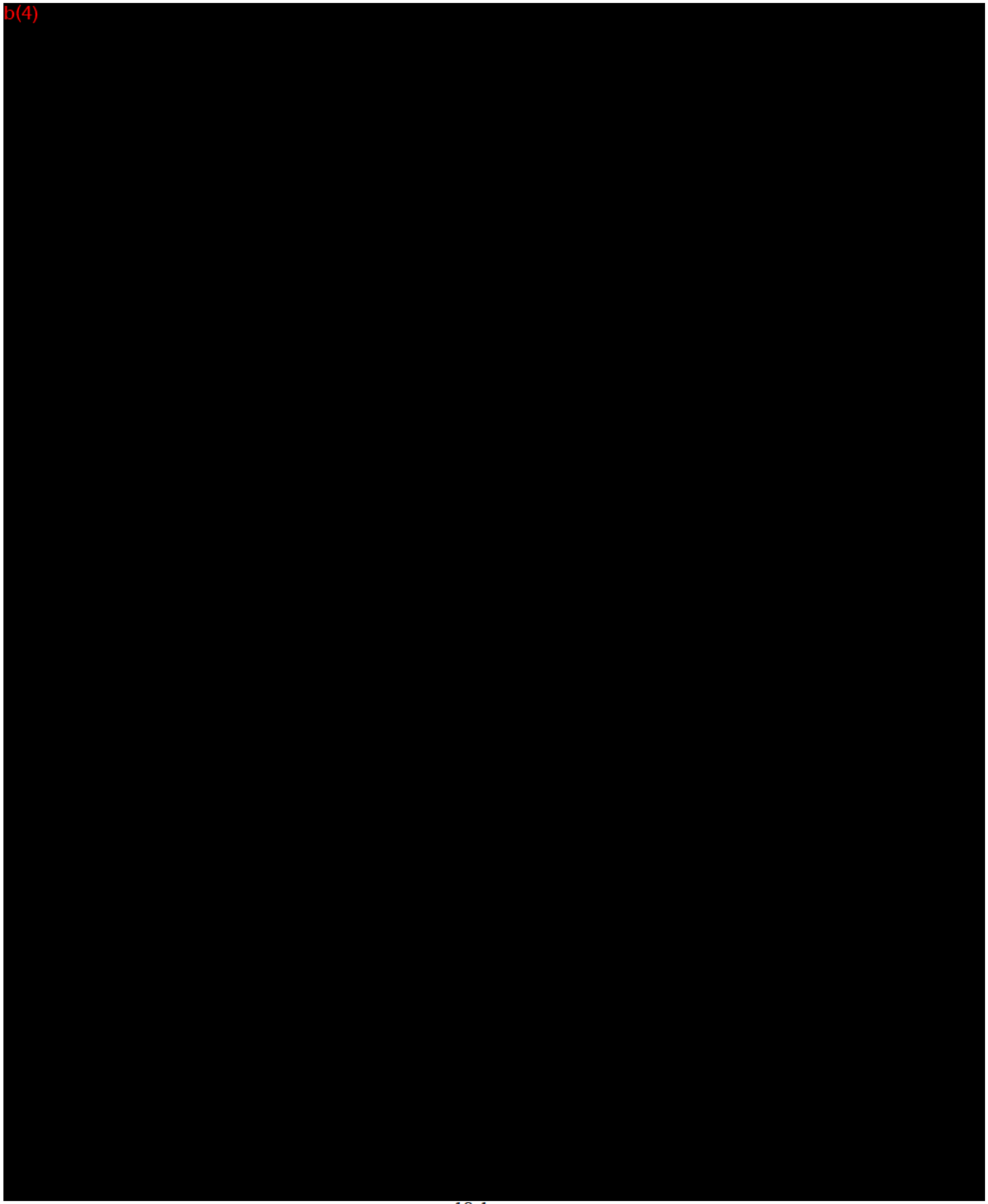
Chapter 17
Electromagnetic Compatibility and Electrical Safety
(Not Applicable)

Chapter 18

Performance Testing-Bench

Performance Testing-Bench

b(4)

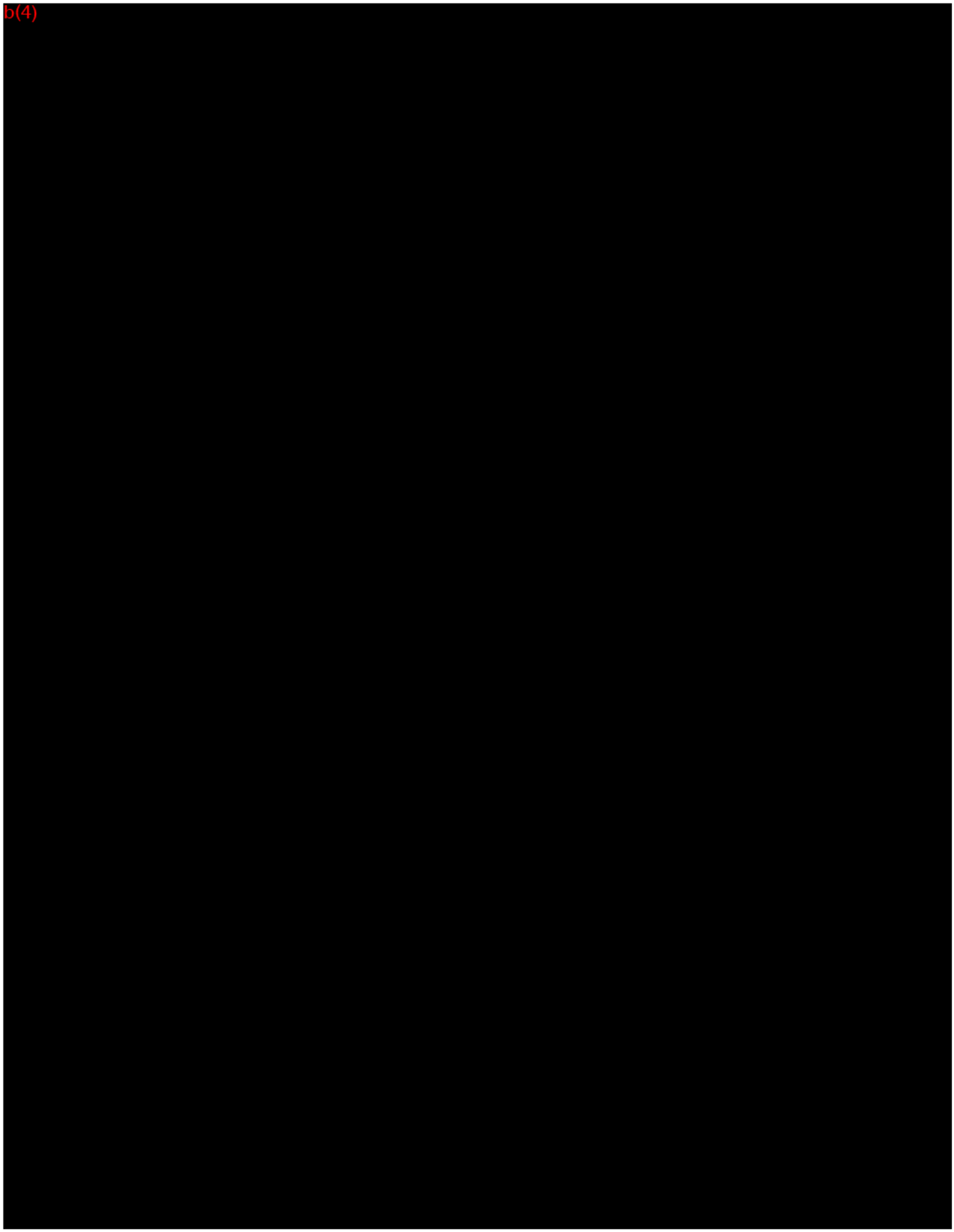



b(4)

Chapter 19

Performance Testing – Animal

b(4)



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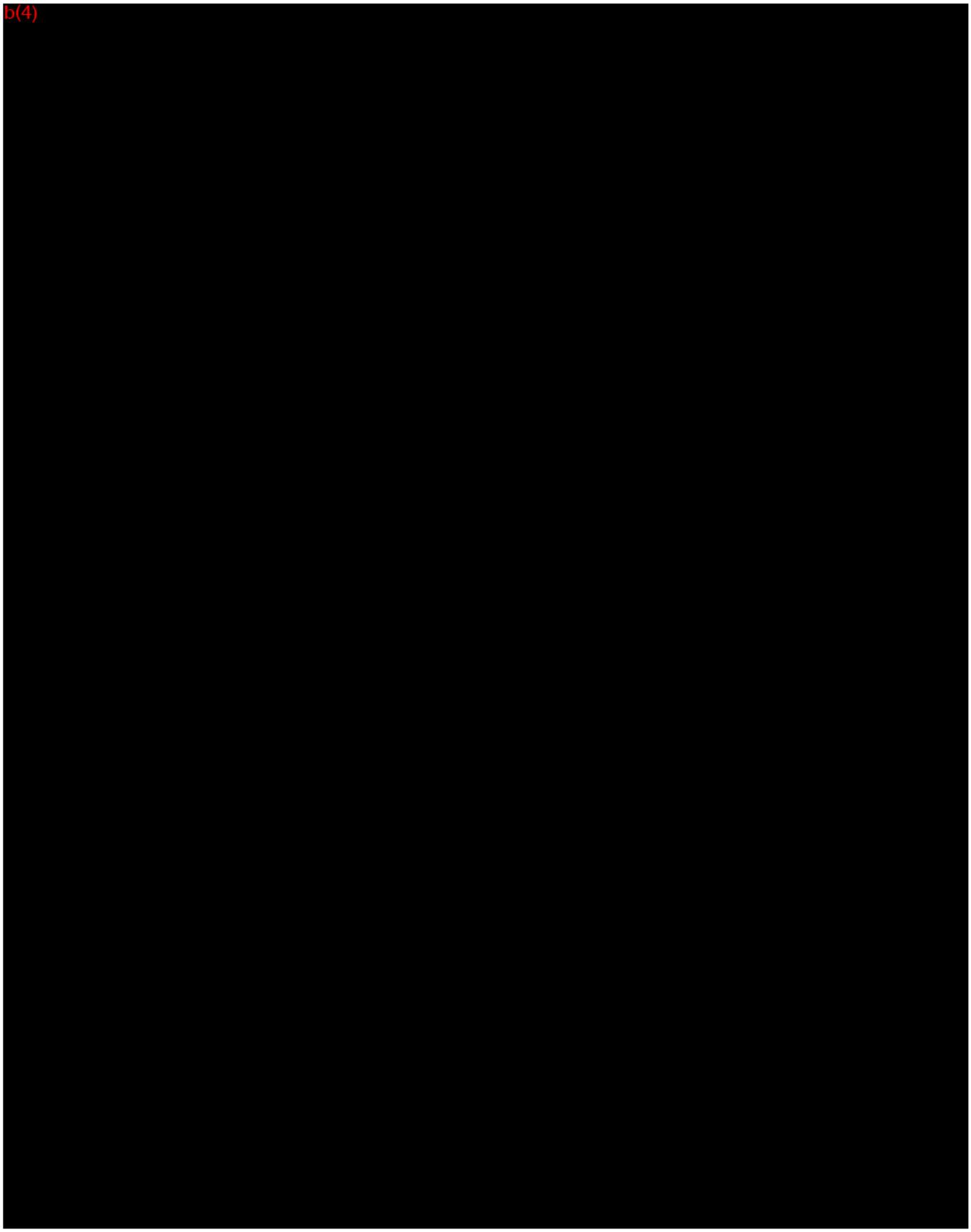

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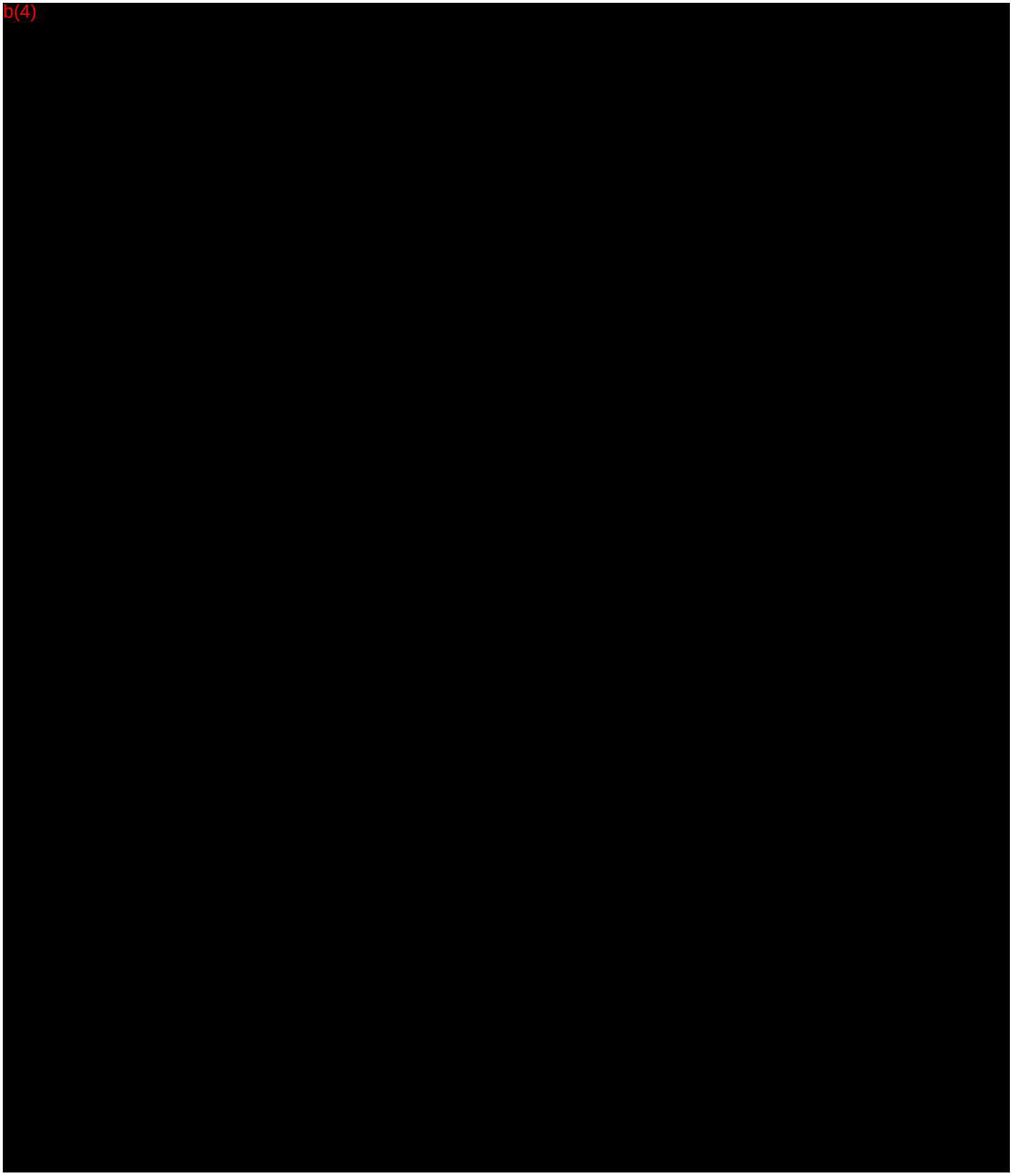

Chapter 20

Performance Testing-Clinical (Not Applicable)

CORELEADER BIOTECH CO., LTD

RISK MANAGEMENT REPORT

(Comply with ISO 14971:2007)

HEMO-Bandage

b(4) [redacted]

Initial Prepare By:	Review By:	Approve By:
(b) (6) [redacted]	Ya-Wen Kuo	Ya-Wen Kuo
Date:2014/12/25	Date:2014/12/26	Date:2014/12/26
Position: Manager, System Compliance	Position: Manager, R&D and Regulatory Affair	Position: Manager, R&D and Regulatory Affair

b(4)Risk Management Analysis

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Annex IV

Cytotoxicity Test Report

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Annex V

Skin Irritation Test Report

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Annex VI

Skin Sensitization Test Report

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Annex VII

Heavy Metal Test Report

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b(6)Personal Information

康力得生技股份有限公司
CoreLeader Biotech CO., LTD
22102 新北市汐止區新台五路一段100號19樓

Re: K151204

Trade Name: CoreLeader HEMO-Bandage

K151204/S001

FDA CDRH DMC
JUL 16 2015
Received

Date: 13th July 2015
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center WO66-G609
10903 New Hampshire Avenue, Silver Spring, Maryland 20993-0002

Traditional 510(k): New Device Submission

Device Name:	CoreLeader HEMO-Bandage
Common Name:	Topical wound dressing
K Number:	K151204
Class	Unclassified
Panel	General & Plastic Surgery
510(k) Submitter:	CoreLeader Biotech Co., Ltd. 19F, No. 100, Sec. 1, Xintai 5th Rd., Xizhi Dist., New Taipei City, Taiwan, R.O.C. 22102 Phone: +886-2-26968880 Fax: +886-2-26968882
Contact Person:	Ya-Wen Kuo Manager, Regulatory Affair 19F, No. 100, Sec. 1, Xintai 5th Rd., Xizhi Dist., New Taipei City, Taiwan, R.O.C. 22102 Phone: +886-2-26968880 FAX: +886-2-26968882 E-mail: ywk@coreleaderbio.com
eCopy Statement:	The eCopy is an exact duplicate of the paper copy.

康力得生技股份有限公司
CoreLeader Biotech CO., LTD
22102 新北市汐止區新台五路一段100號19樓

Dear Dr. Arepalli,

b(4)

[redacted]

康力得生技股份有限公司
CoreLeader Biotech CO., LTD
22102 新北市汐止區新台五路一段100號19樓

b(4)

[redacted]

康力得生技股份有限公司
CoreLeader Biotech CO., LTD
22102 新北市汐止區新台五路一段100號19樓

b(4)

[redacted]

Sincerely,

Ya-Wen Kuo

Ya-Wen Kuo
Manager, Regulatory Affair
CoreLeader Biotech Co., Ltd

Content

Chapter 3

510(k) Cover Letter

康力得生技股份有限公司
CoreLeader Biotech CO., LTD
22102 新北市汐止區新台五路一段100號19樓

Re: K151204

Trade Name: CoreLeader HEMO-Bandage

Date: 13th July 2015
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center WO66-G609
10903 New Hampshire Avenue, Silver Spring, Maryland 20993-0002

Traditional 510(k): New Device Submission

Device Name:	CoreLeader HEMO-Bandage
Common Name:	Topical wound dressing
K Number:	K151204
Class	Unclassified
Panel	General & Plastic Surgery
510(k) Submitter:	CoreLeader Biotech Co., Ltd. 19F, No. 100, Sec. 1, Xintai 5th Rd., Xizhi Dist., New Taipei City, Taiwan, R.O.C. 22102 Phone: +886-2-26968880 Fax: +886-2-26968882
Contact Person:	Ya-Wen Kuo Manager, Regulatory Affair 19F, No. 100, Sec. 1, Xintai 5th Rd., Xizhi Dist., New Taipei City, Taiwan, R.O.C. 22102 Phone: +886-2-26968880 FAX: +886-2-26968882 E-mail: ywk@coreleaderbio.com
eCopy Statement:	The eCopy is an exact duplicate of the paper copy.

康力得生技股份有限公司
CoreLeader Biotech CO., LTD
22102 新北市汐止區新台五路一段100號19樓

Dear Dr. Arepalli,

b(4)

[redacted]

康力得生技股份有限公司
CoreLeader Biotech CO., LTD
22102 新北市汐止區新台五路一段100號19樓

b(4)

[redacted]

康力得生技股份有限公司
CoreLeader Biotech CO., LTD
22102 新北市汐止區新台五路一段100號19樓

b(4)

[redacted]

Sincerely,

Ya-Wen Kuo

Ya-Wen Kuo
Manager, Regulatory Affair
CoreLeader Biotech Co., Ltd

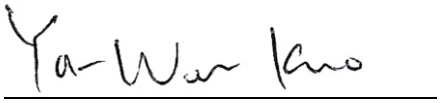
康力得生技股份有限公司
CoreLeader Biotech CO., LTD
22102 新北市汐止區新台五路一段100號19樓

Chapter 6

Truthful and Accurate Statement

Truthful and Accurate Statement

I certify that, in my capacity as a Director of Regulatory and R&D of CoreLeader Biotech Co., Ltd, I believe, to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



Ya-Wen Kuo
Director, Regulatory and R&D
CoreLeader Biotech Co., Ltd

Ya-Wen Kuo
Typed Name

2015/07/14
Date

K151204
*(Premarket Notification [510(k)] Number)

*For a new submission, leave the 510(k) number blank.

Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not a consultant for the 510(k) submitter].

b(4)Testing

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康力得生技股份有限公司
CoreLeader Biotech CO., LTD
19F., No.100, Sec. 1, Xintai 5th Rd., Xizhi Dist., New Taipei City 22102, Taiwan (R.O.C.)

Declaration Letter

To whom it may concern,

CoreLeader Biotech Co., Ltd will not make any claims of antimicrobial indication on future product labeling of HEMO-Bandage.

Ya-Wen Kuo

Ya-Wen Kuo
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